US011672288B2

(12) **United States Patent**
Albaugh et al.

(10) **Patent No.: US 11,672,288 B2**
(45) **Date of Patent: Jun. 13, 2023**

(54) **MATTER OF MANUFACTURE OF COMPRESSION LEGGING SYSTEM AND ASSOCIATED USES**

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(72) Inventors: **Matthew Albaugh**, Lafayette, IN (US); **Pablo Argote**, Boulder, CO (US); **Neal Patel**, Chesterton, IN (US); **Raj Patel**, Wilmette, IL (US); **Sriram Boppana**, Arlington Heights, IL (US); **Alexander Ocken**, West Lafayette, IN (US); **Axel Masquelin**, Carmel, IN (US); **Orlando Hoilett**, West Lafayette, IN (US); **David Miller**, Evanston, IL (US); **Michael Drakopoulos**, Wauwatosa, WI (US)

(73) Assignee: **Predictive Wear**, Lafayette, IN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **17/003,906**

(22) Filed: **Aug. 26, 2020**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(Continued)

(51) **Int. Cl.**
A41D 13/12 (2006.01)
A61B 5/00 (2006.01)

(Continued)

(52) **U.S. Cl.**
CPC *A41D 13/1281* (2013.01); *A41D 13/1254* (2013.01); *A41D 17/02* (2013.01); *A61B 5/0535* (2013.01); *A61B 5/1116* (2013.01); *A61B 5/6804* (2013.01); *A61B 5/7264* (2013.01); *A41D 2400/38* (2013.01)

(58) **Field of Classification Search**
None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,308,294 B2 12/2007 Hassonjee et al.
7,474,910 B2 1/2009 Hassonjee et al.

(Continued)

FOREIGN PATENT DOCUMENTS

WO 20180209100 A1 11/2018

OTHER PUBLICATIONS

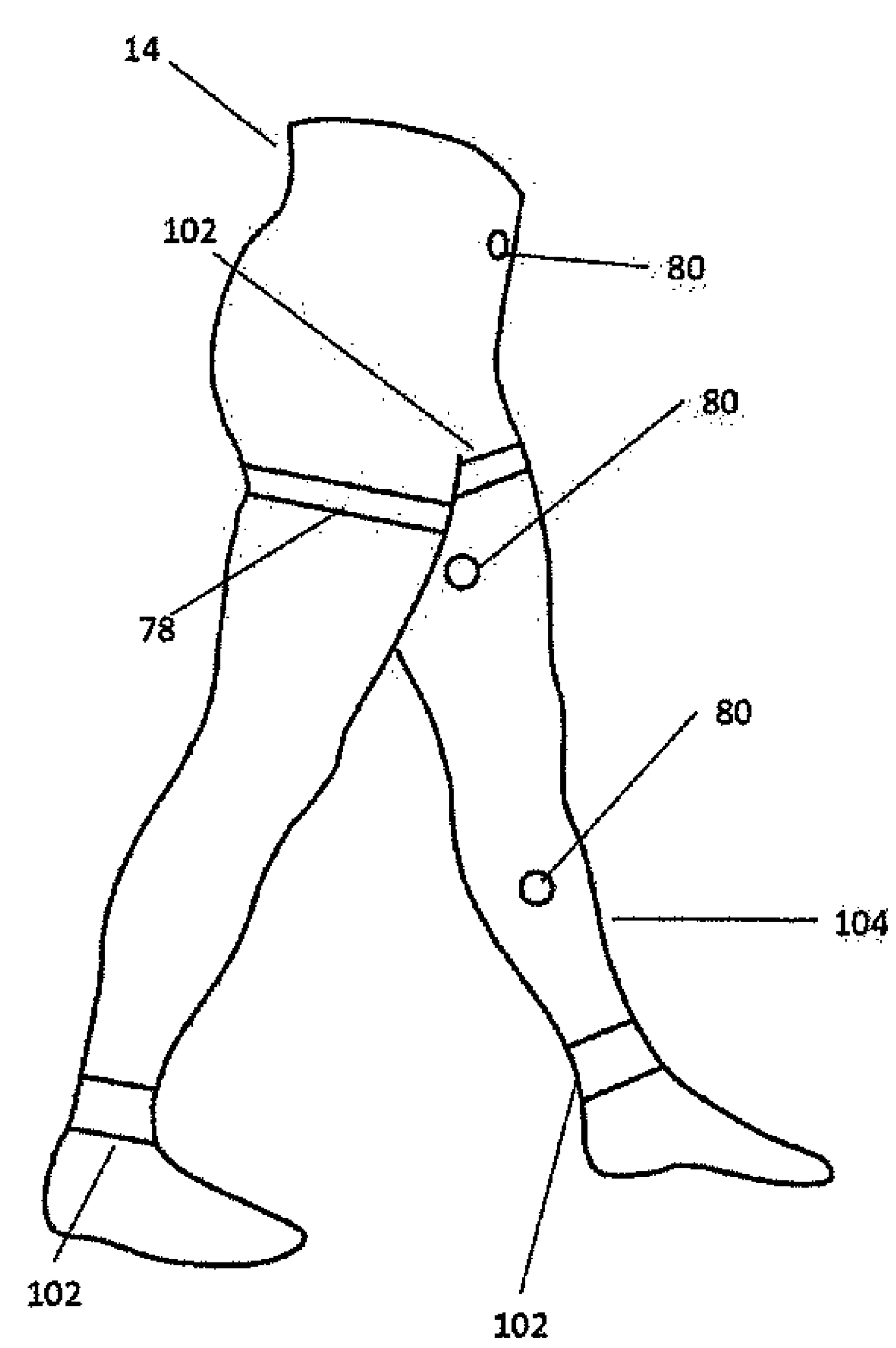
WIPO, Notification of Transmittal of the International Search Report and the Written Opinion of the International Searching Authority, dated Aug. 10, 2020, 14 pages.

Primary Examiner — Benjamin S Melhus
(74) *Attorney, Agent, or Firm* — Gutwein Law; Tyler B. Droste

(57) **ABSTRACT**

Described herein, is the manufacture, matter of compositions, function, methods and uses of a compression legging system that combines a swelling monitor, a patient activity monitor, medical compression legging material, and a mobile application to help PTS patients detect recurrent DVT and seek medical attention quickly before the development of PE, while reducing swelling and preventing DVT via compression therapy.

7 Claims, 28 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 62/813,887, filed on Mar. 5, 2019.

(51) **Int. Cl.**

A41D 17/02	(2006.01)
A61B 5/11	(2006.01)
A61B 5/0535	(2021.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,878,030	B2	2/2011	Burr		
7,966,052	B2	6/2011	DeFusco et al.		
7,970,451	B2	6/2011	Hassonjee et al.		
8,082,762	B2	12/2011	Burr		
8,214,008	B2	7/2012	Hassonjee et al.		
2006/0058593	A1*	3/2006	Drinan	A61B 5/685	600/301
2009/0234262	A1	9/2009	Reid, Jr. et al.		
2009/0287191	A1*	11/2009	Ferren	A61B 5/02055	604/891.1
2011/0060239	A1	3/2011	Gaw		
2015/0057585	A1	2/2015	Ladd		
2015/0272482	A1*	10/2015	Houmanfar	A61B 5/0531	600/595
2015/0272483	A1*	10/2015	Etemad	H04B 1/3888	600/595
2015/0272501	A1*	10/2015	Maceachern	A61B 5/6823	600/301
2015/0366504	A1*	12/2015	Connor	A61B 5/6804	600/301
2016/0135706	A1	5/2016	Sullivan et al.		
2016/0242646	A1	8/2016	Obma		
2016/0278642	A1	9/2016	Vogel et al.		
2016/0324442	A1	11/2016	Zdeblick		
2016/0338644	A1*	11/2016	Connor	A61B 5/11	
2017/0196502	A1	7/2017	Watson et al.		
2017/0196513	A1	7/2017	Longinotti-Buitoni et al.		
2017/0354372	A1	12/2017	Varadan et al.		
2018/0081439	A1*	3/2018	Daniels	G06F 1/163	
2019/0083784	A1*	3/2019	Raghunathan	A61N 1/36034	
2019/0261874	A1*	8/2019	Berg	A61B 5/0205	
2019/0328330	A1*	10/2019	Inan	A61B 5/7221	
2019/0346925	A1*	11/2019	Daniels	G06F 3/013	
2020/0113773	A1*	4/2020	Raman	A61H 9/0092	
2020/0261023	A1*	8/2020	Werbin	A41D 1/002	
2020/0393905	A1*	12/2020	Daniels	G06F 3/012	

* cited by examiner

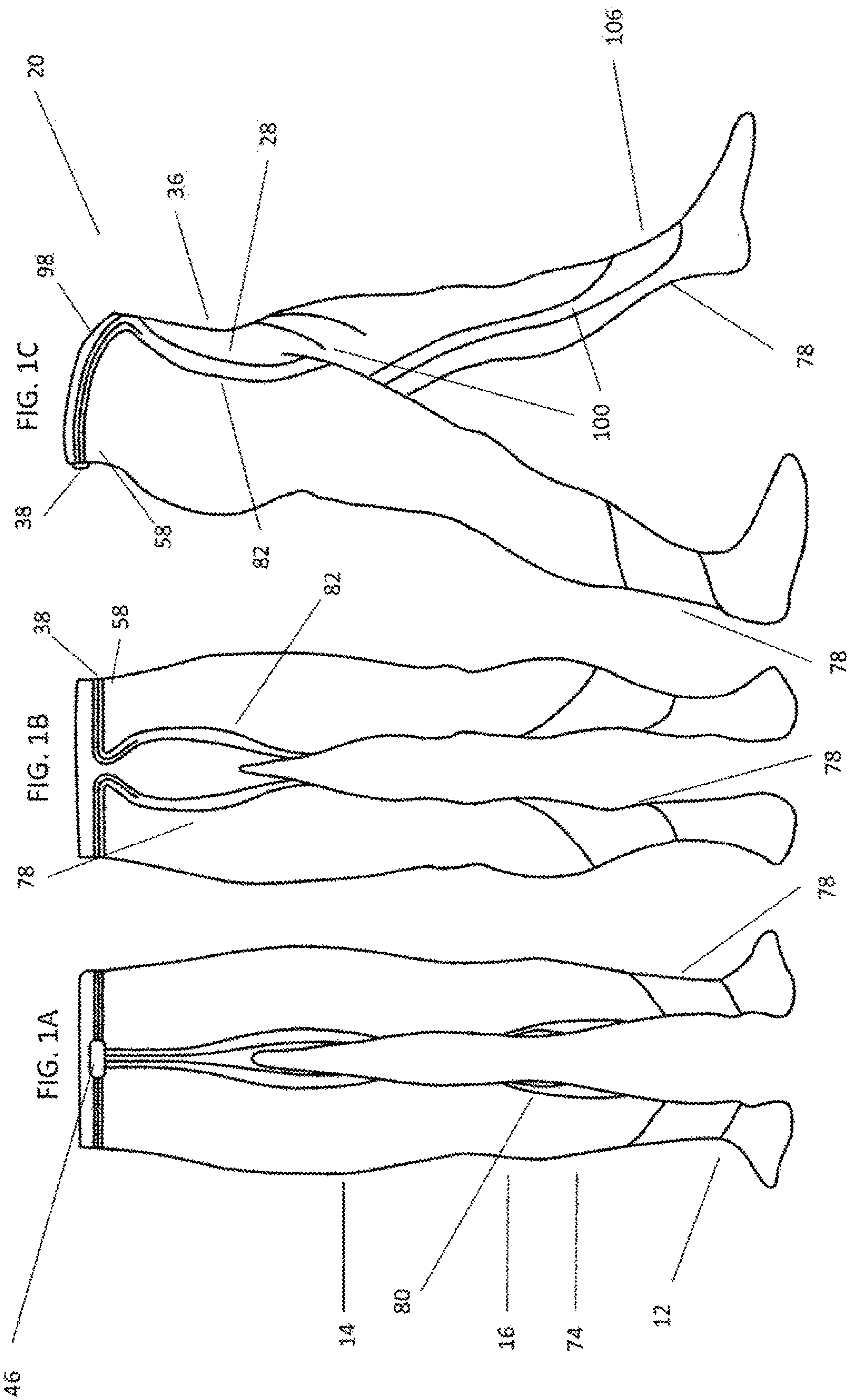
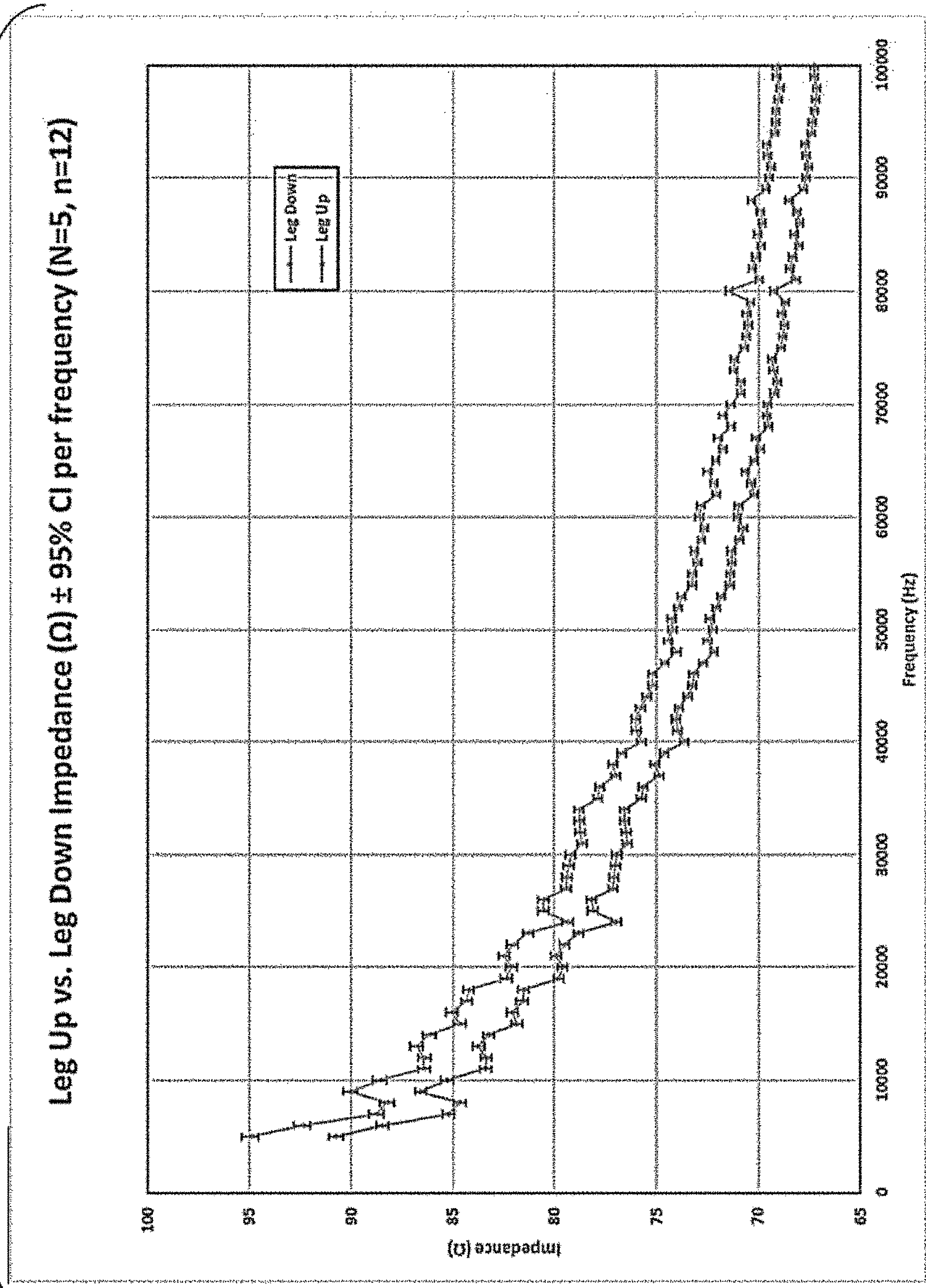


FIG. 1A
FIG. 1B
FIG. 1C
20
106
28
36
98
78
100
38
58
82
78
82
38
58
78
78
78
46
14
80
16
74
12

FIG. 2

96

23


Leg Up vs. Leg Down Impedance (Ω) ± 95% CI per frequency (N=5, n=12)
Leg Down
Leg Up
Impedance (Ω)
100
95
90
85
80
75
70
65
Frequency (Hz)
0
10000
20000
30000
40000
50000
60000
70000
80000
90000
100000

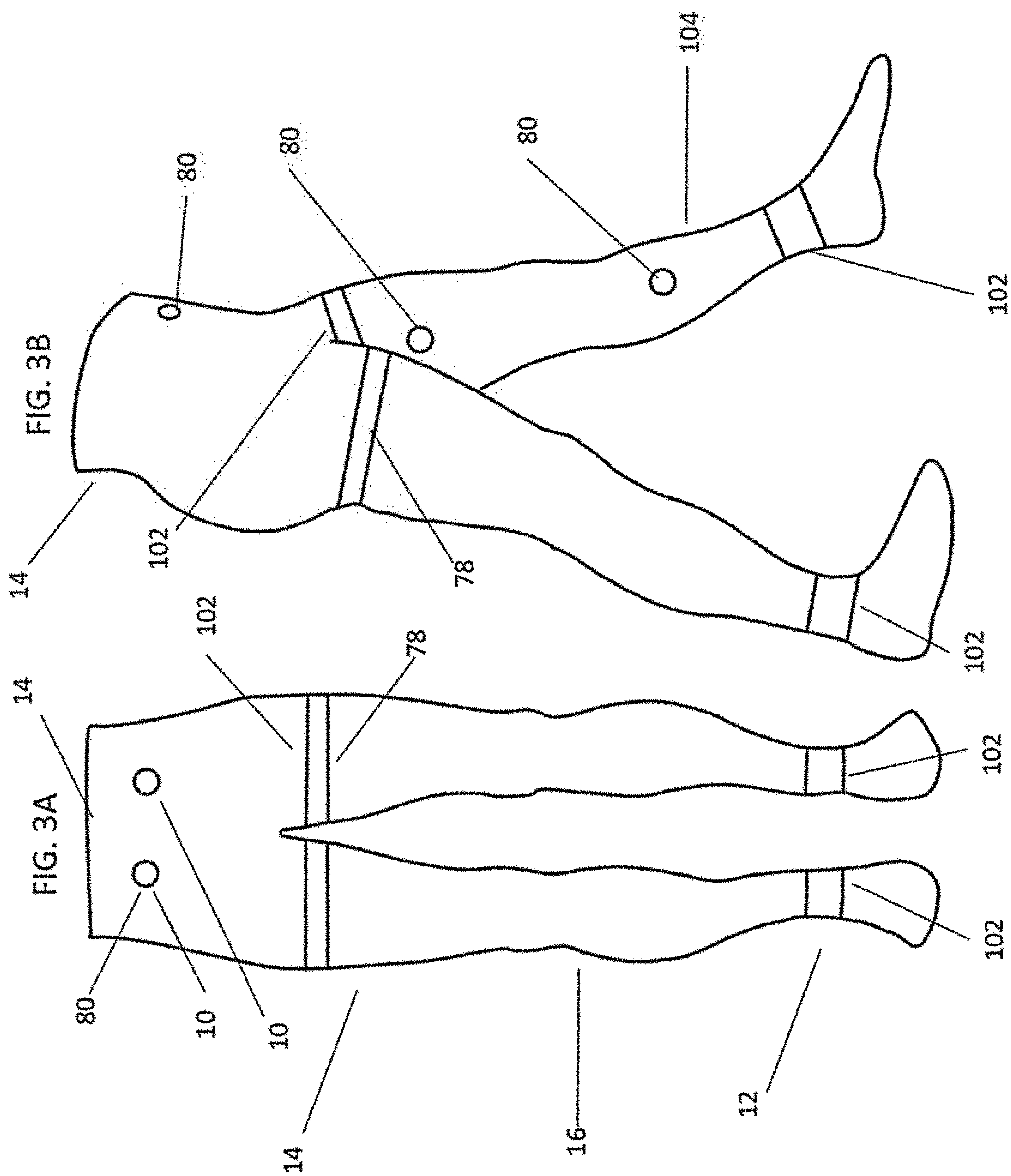


FIG. 3A
FIG. 3B
14
80
10
102
78
16
12
104

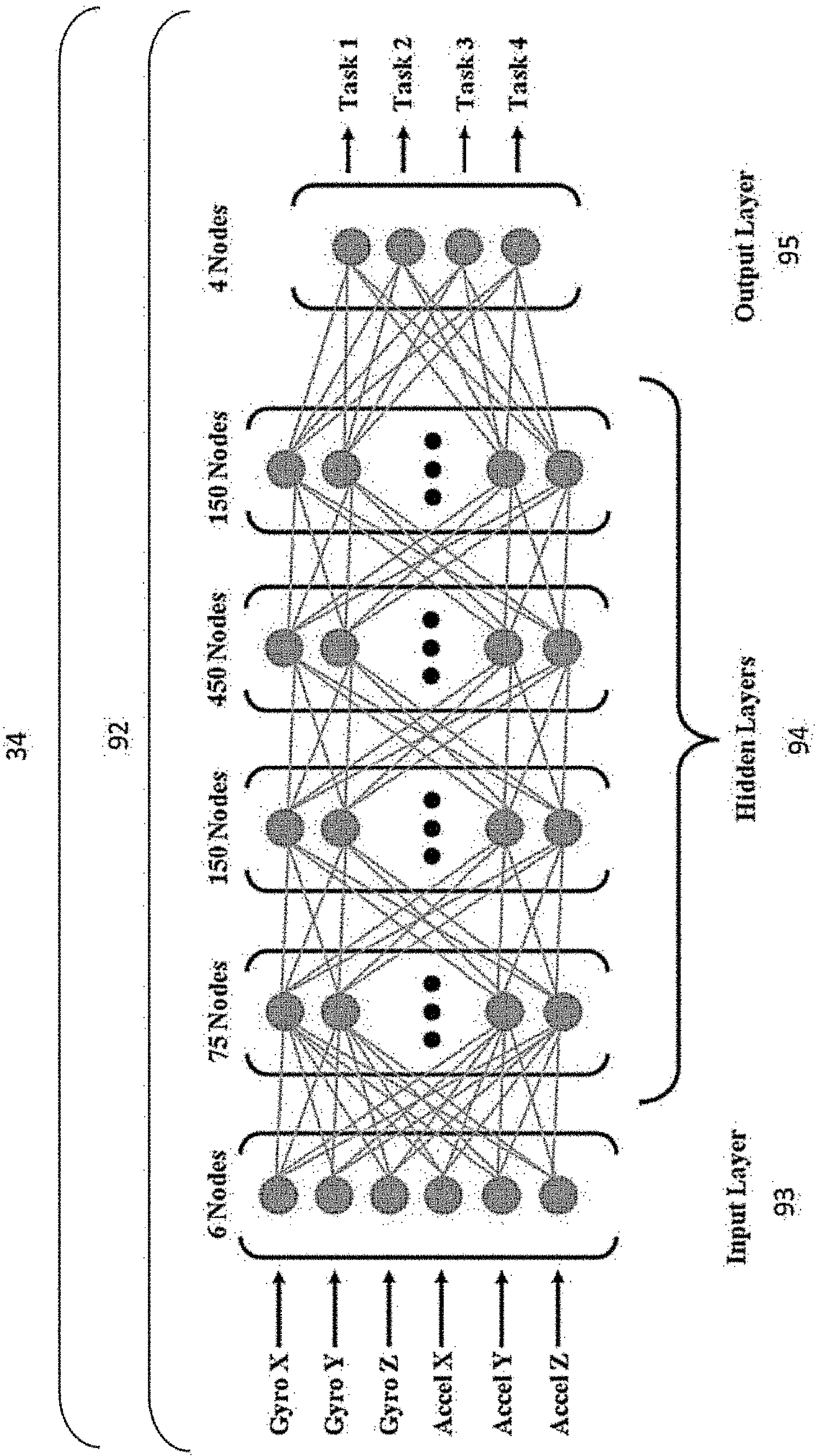

34
92
Task 1
Task 2
Task 3
Task 4
4 Nodes
150 Nodes
450 Nodes
150 Nodes
75 Nodes
6 Nodes
Output Layer
95
Hidden Layers
94
Input Layer
93
Gyro X
Gyro Y
Gyro Z
Accel X
Accel Y
Accel Z

FIG. 4

26

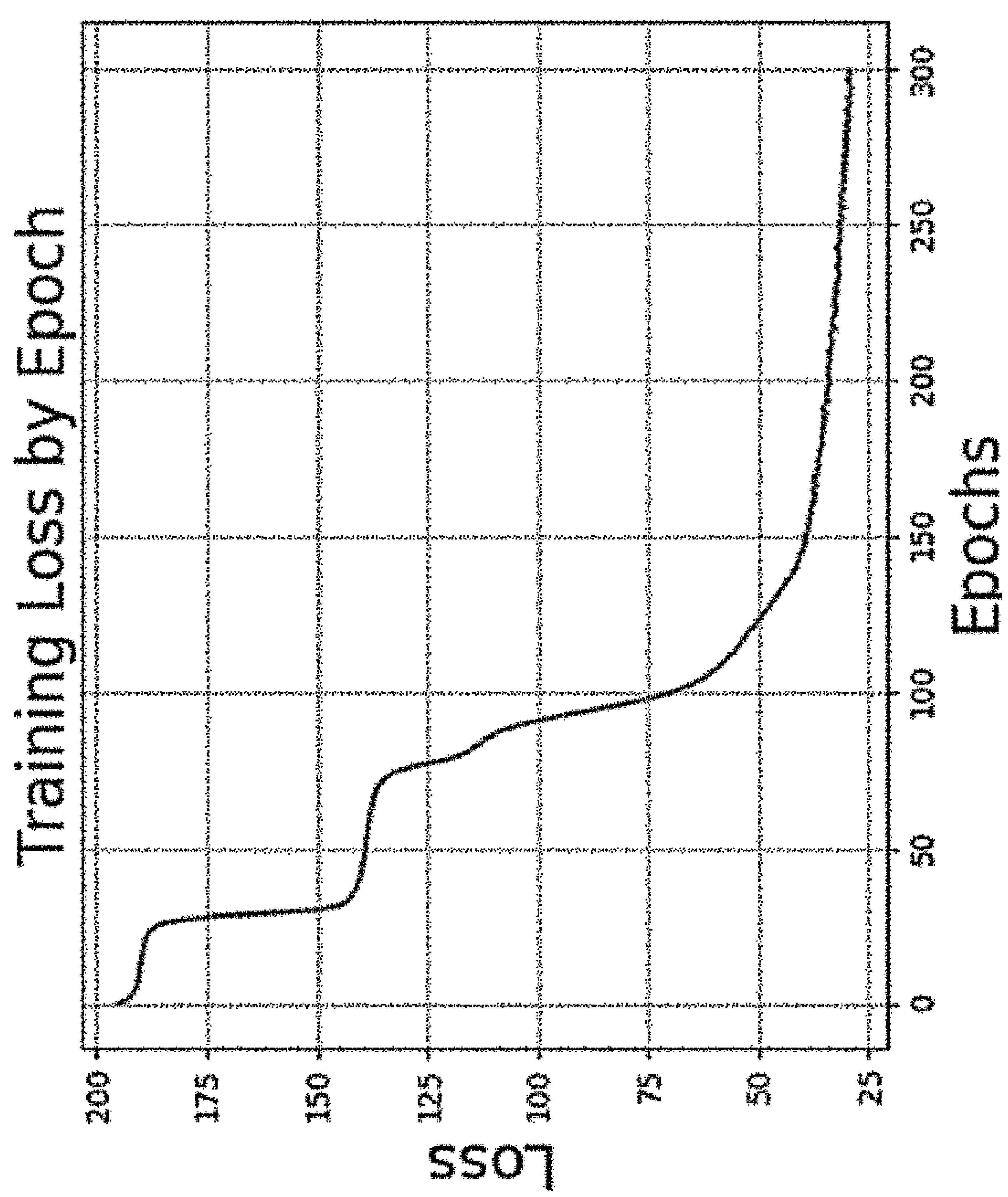


FIG. 5A

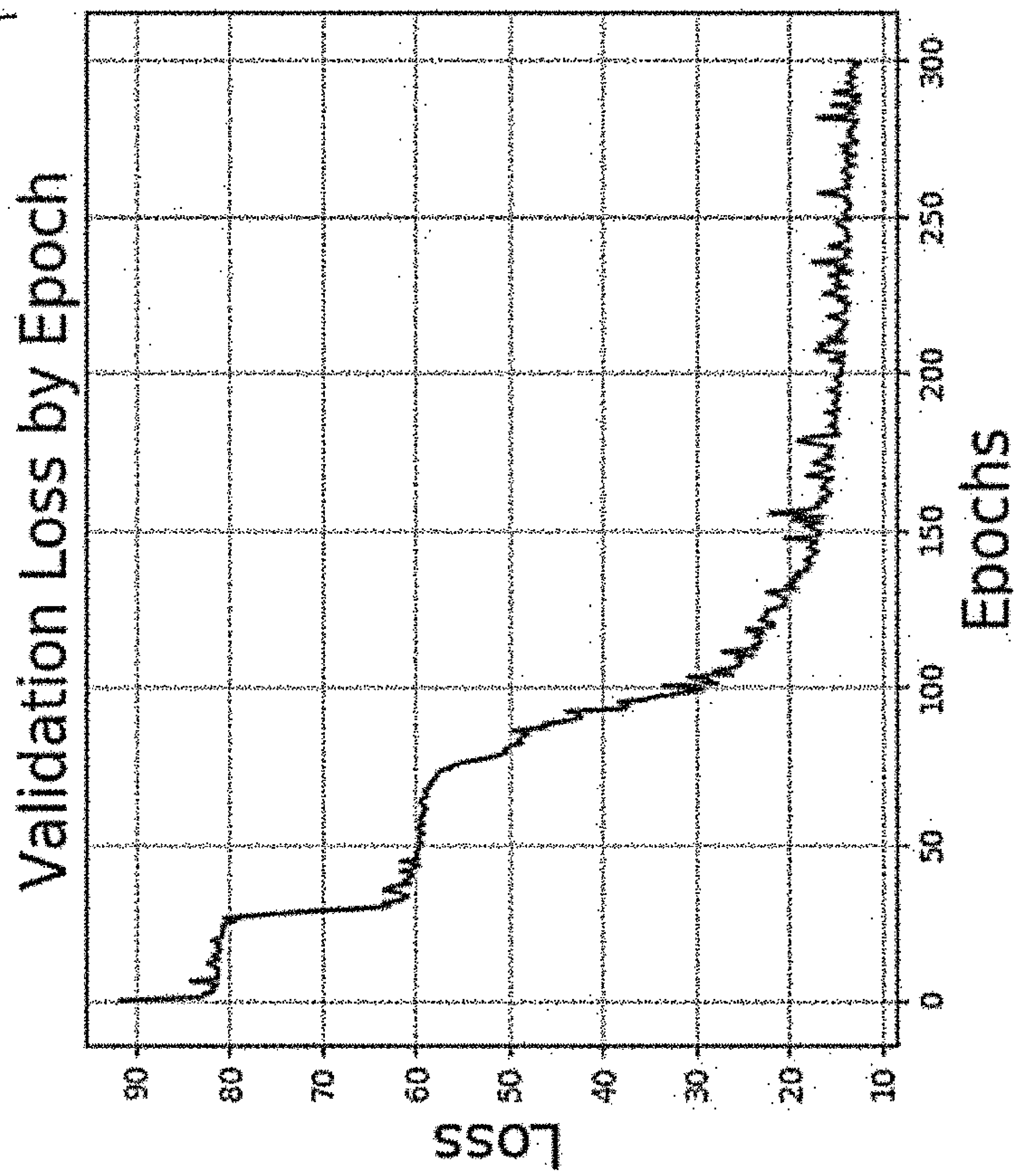


FIG. 5B

26

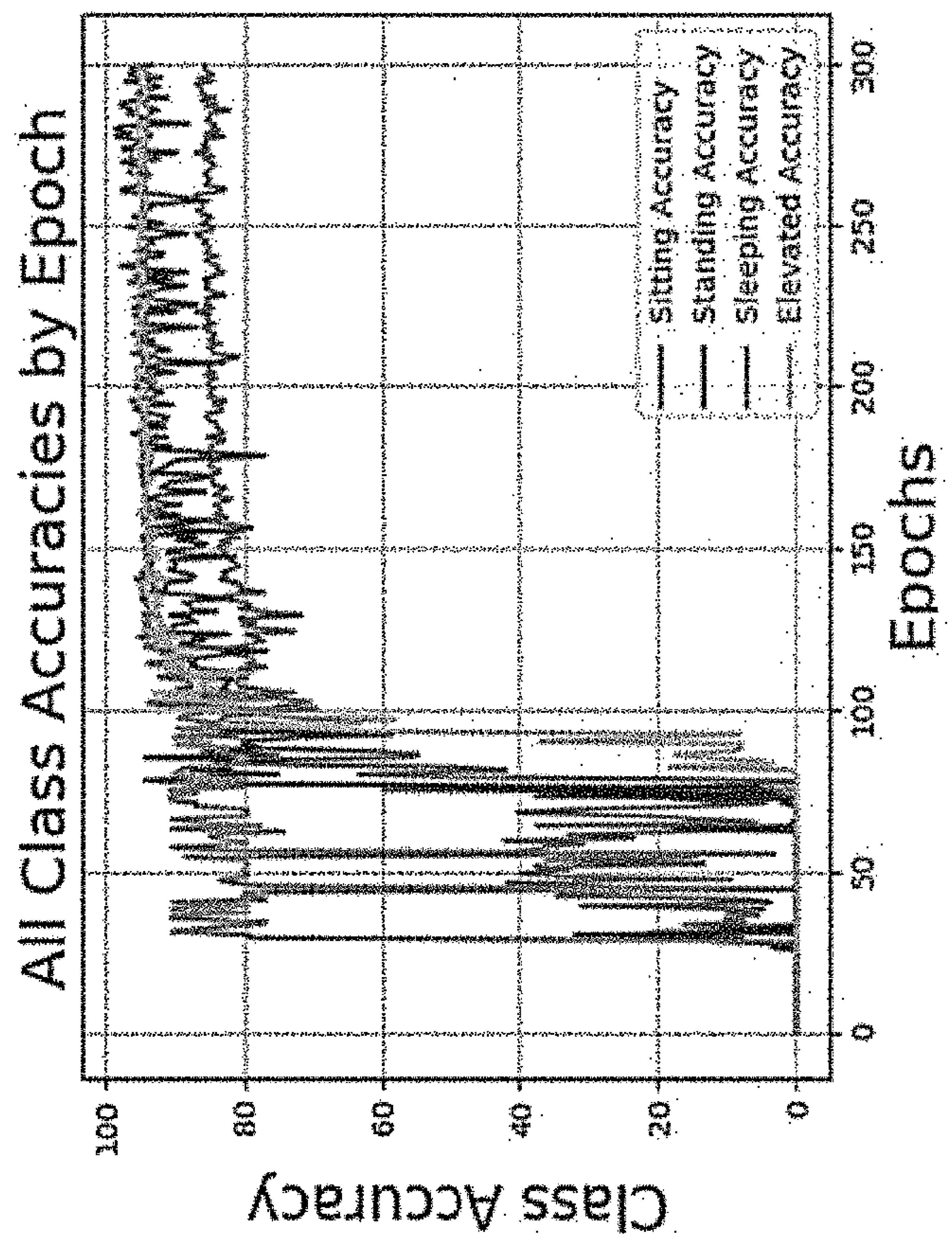


FIG. 6B

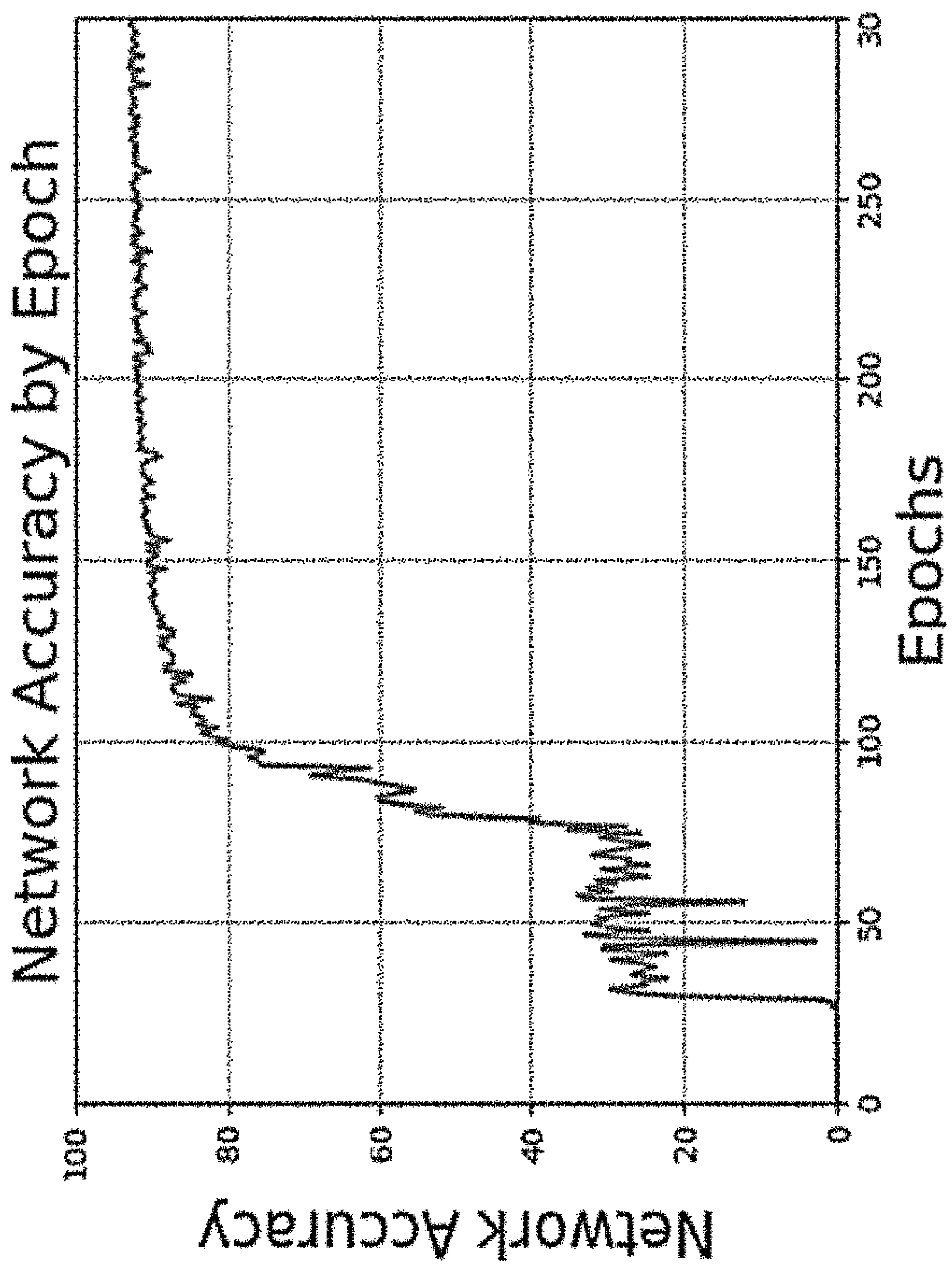


FIG. 6A

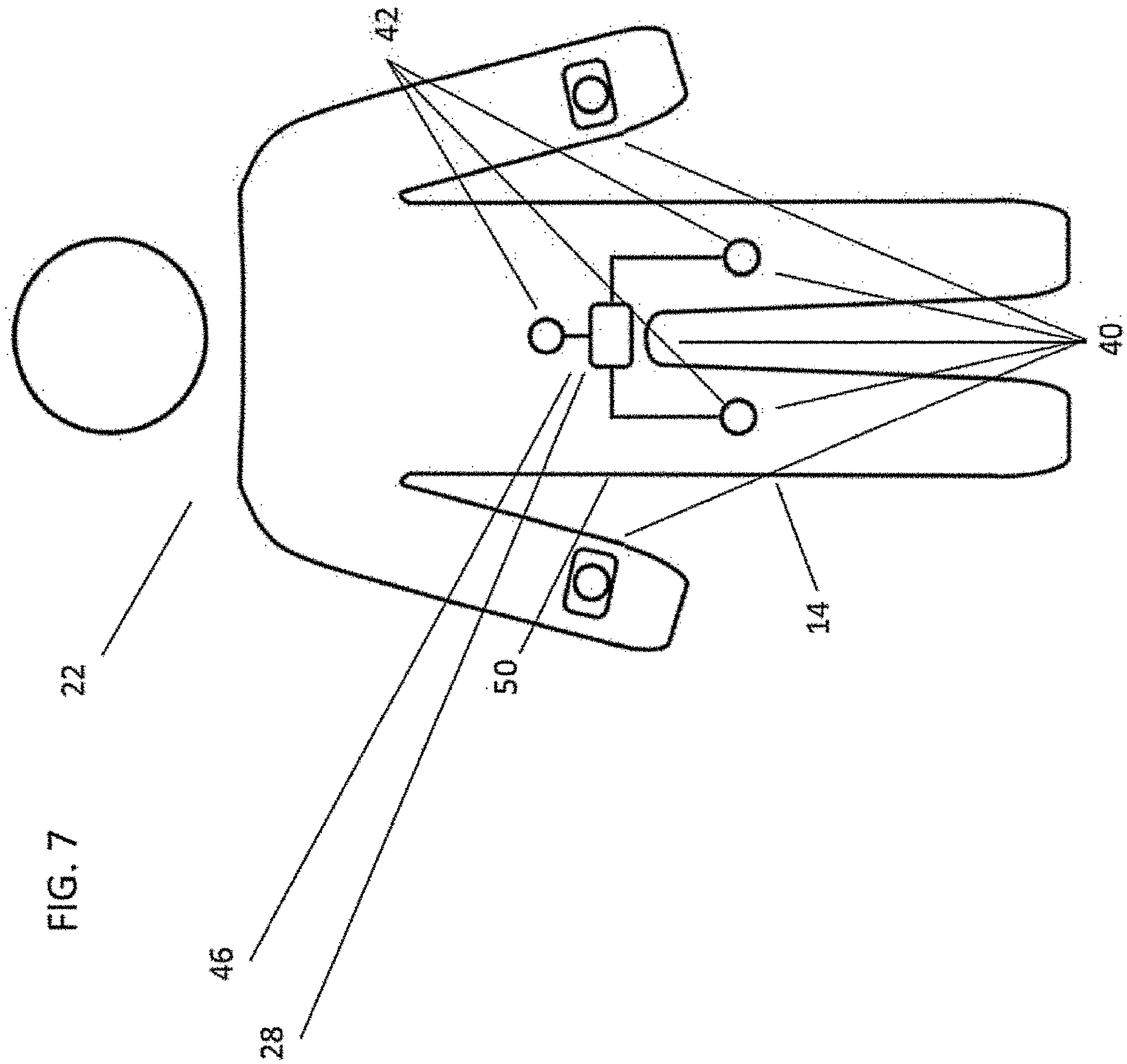


FIG. 7

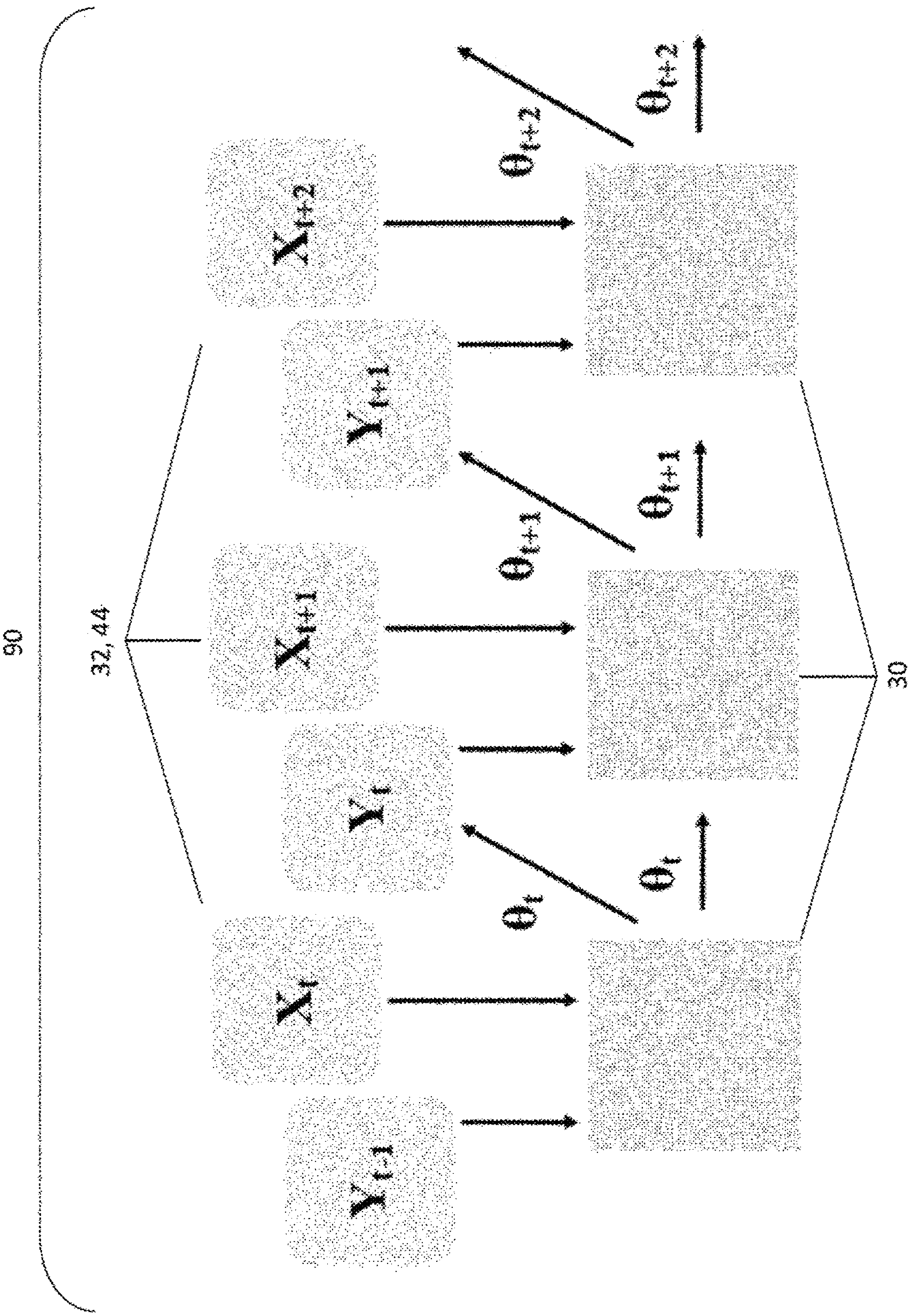

90
32, 44
30
Y_{t-1}
X_t
Y_t
X_{t+1}
Y_{t+1}
X_{t+2}
θ_t
θ_t
θ_{t+1}
θ_{t+1}
θ_{t+2}
θ_{t+2}

FIG. 8

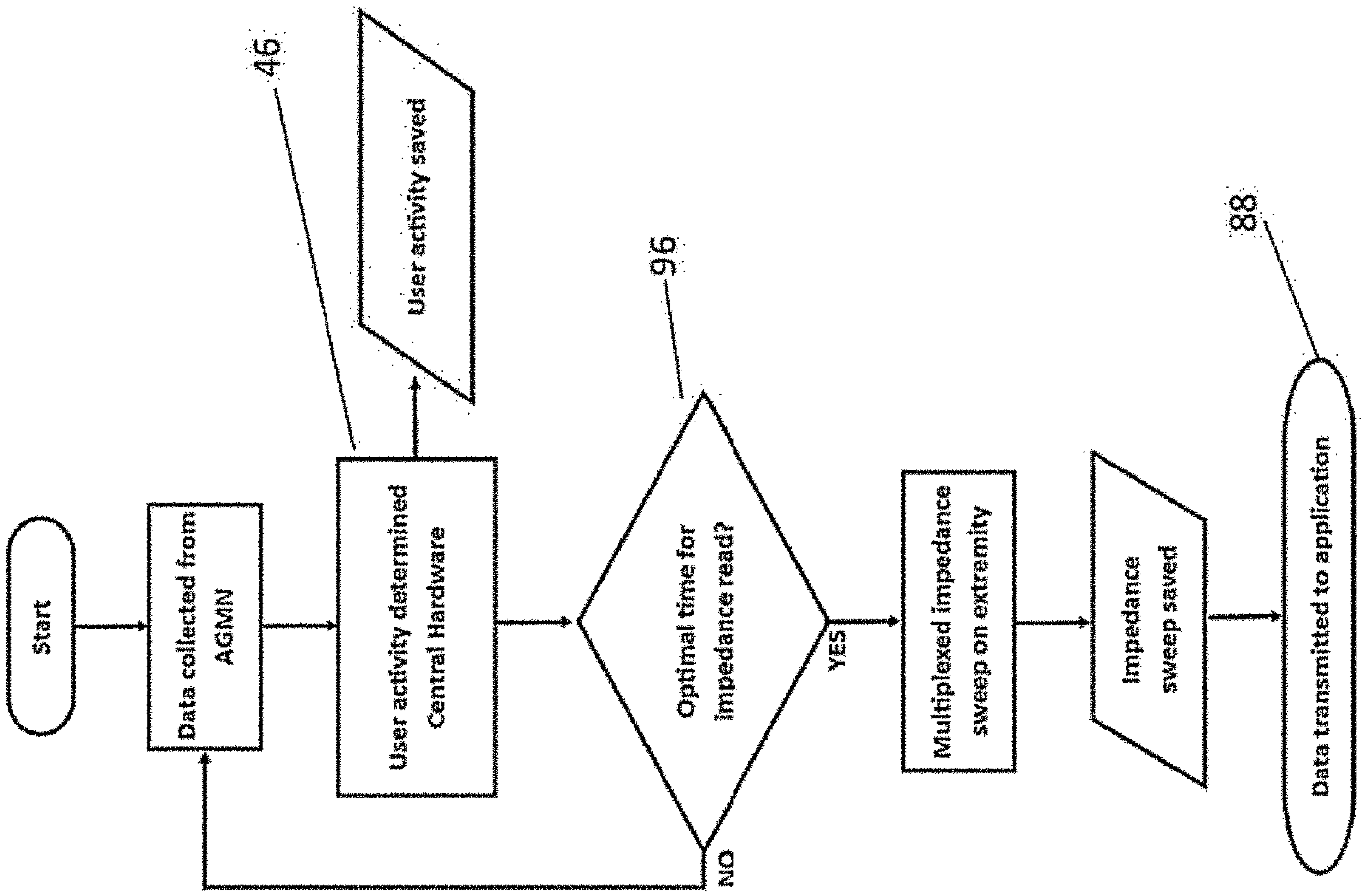

Start
Data collected from AGMN
46
User activity determined Central Hardware
User activity saved
96
Optimal time for impedance read?
YES
NO
Multiplexed impedance sweep on extremity
Impedance sweep saved
88
Data transmitted to application

FIG. 9

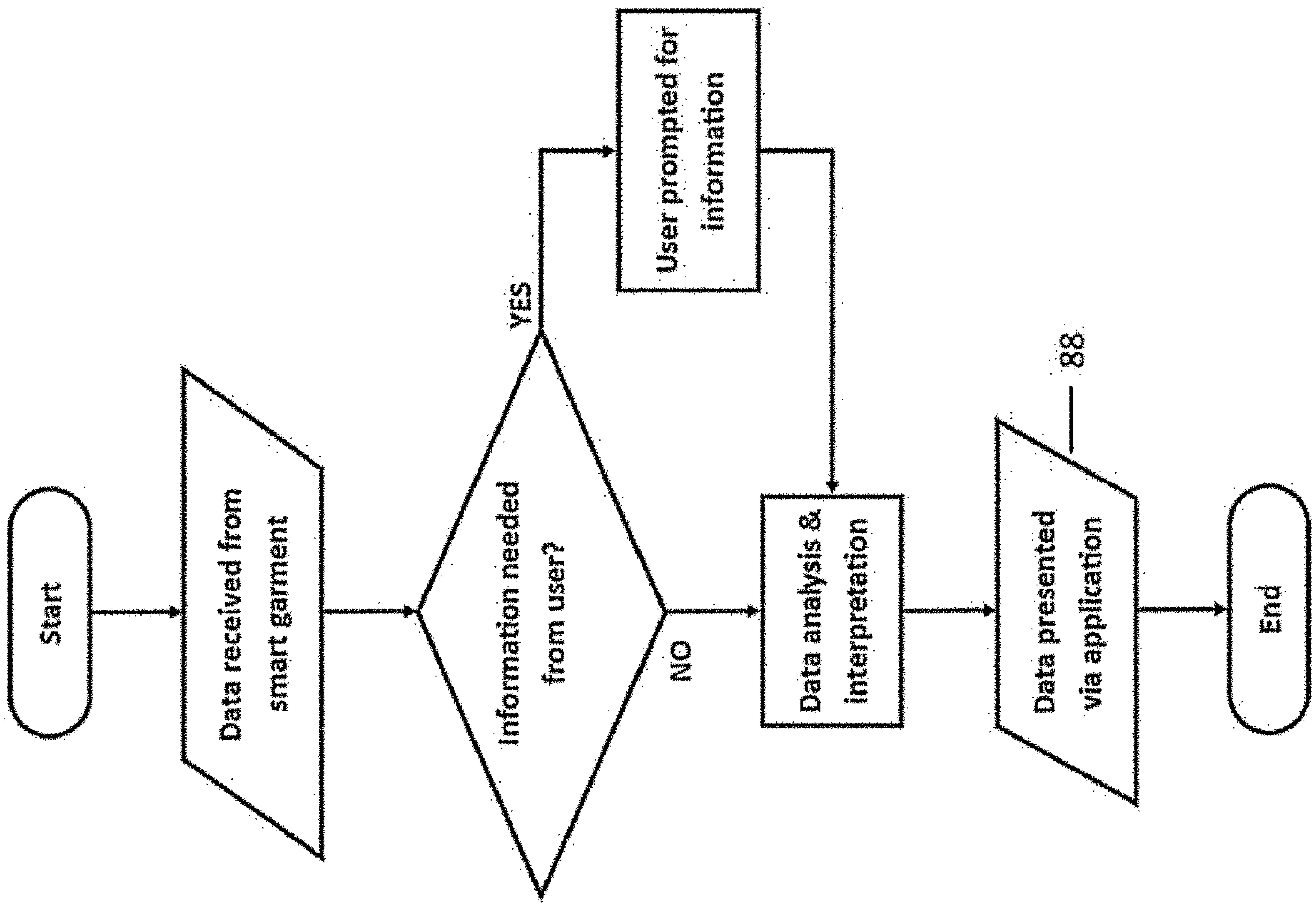

Start
Data received from smart garment
Information needed from user?
YES
NO
User prompted for information
Data analysis & interpretation
88
Data presented via application
End

FIG. 10

FIG. 11A

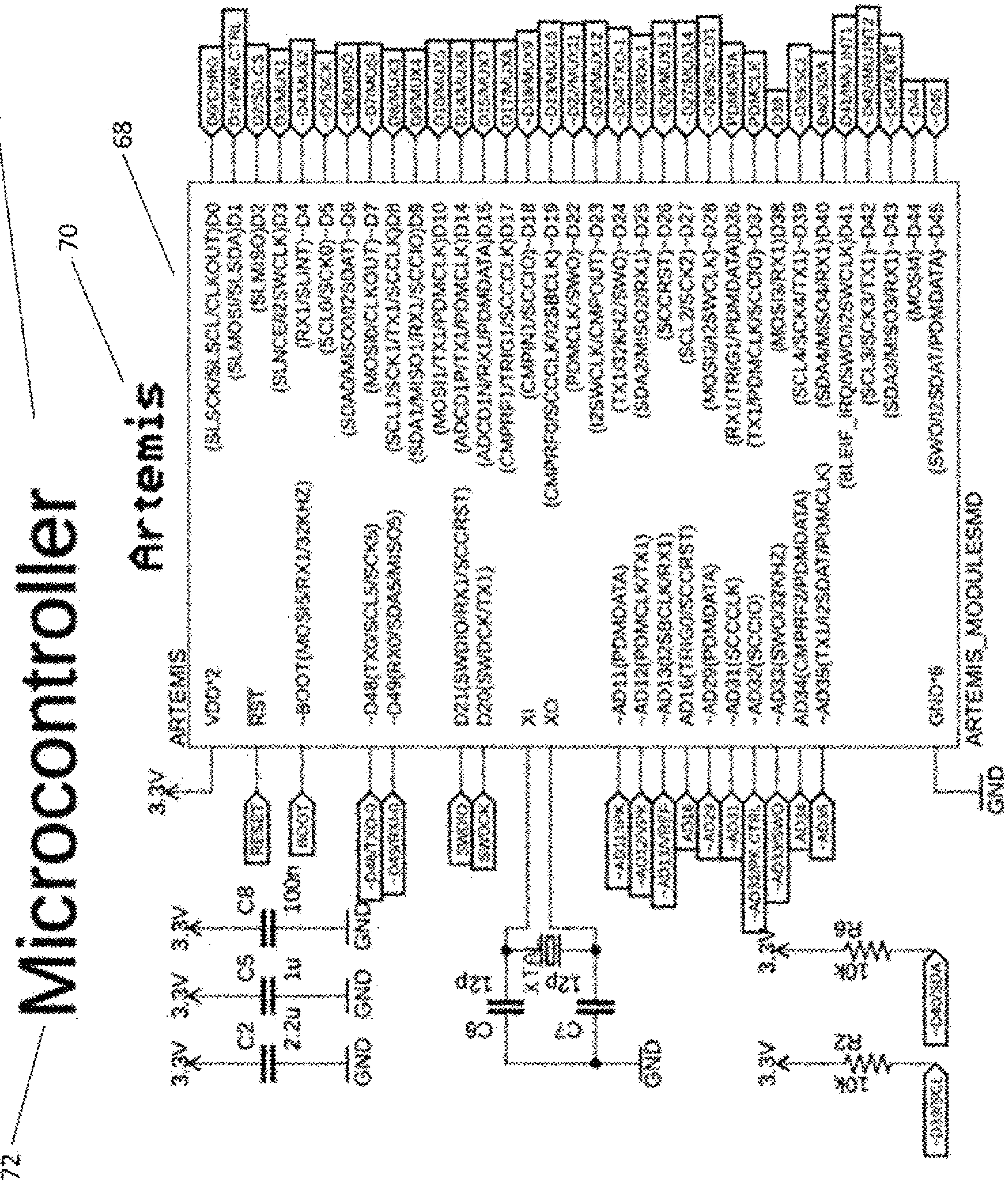

Microcontroller
Artemis
72
26
70
68
ARTEMIS
ARTEMIS_MODULESMD
3.3V
GND
C2
2.2u
C5
1u
C8
100n
C6
C7
12p
XT1
R2
R6
10K

FIG. 11B

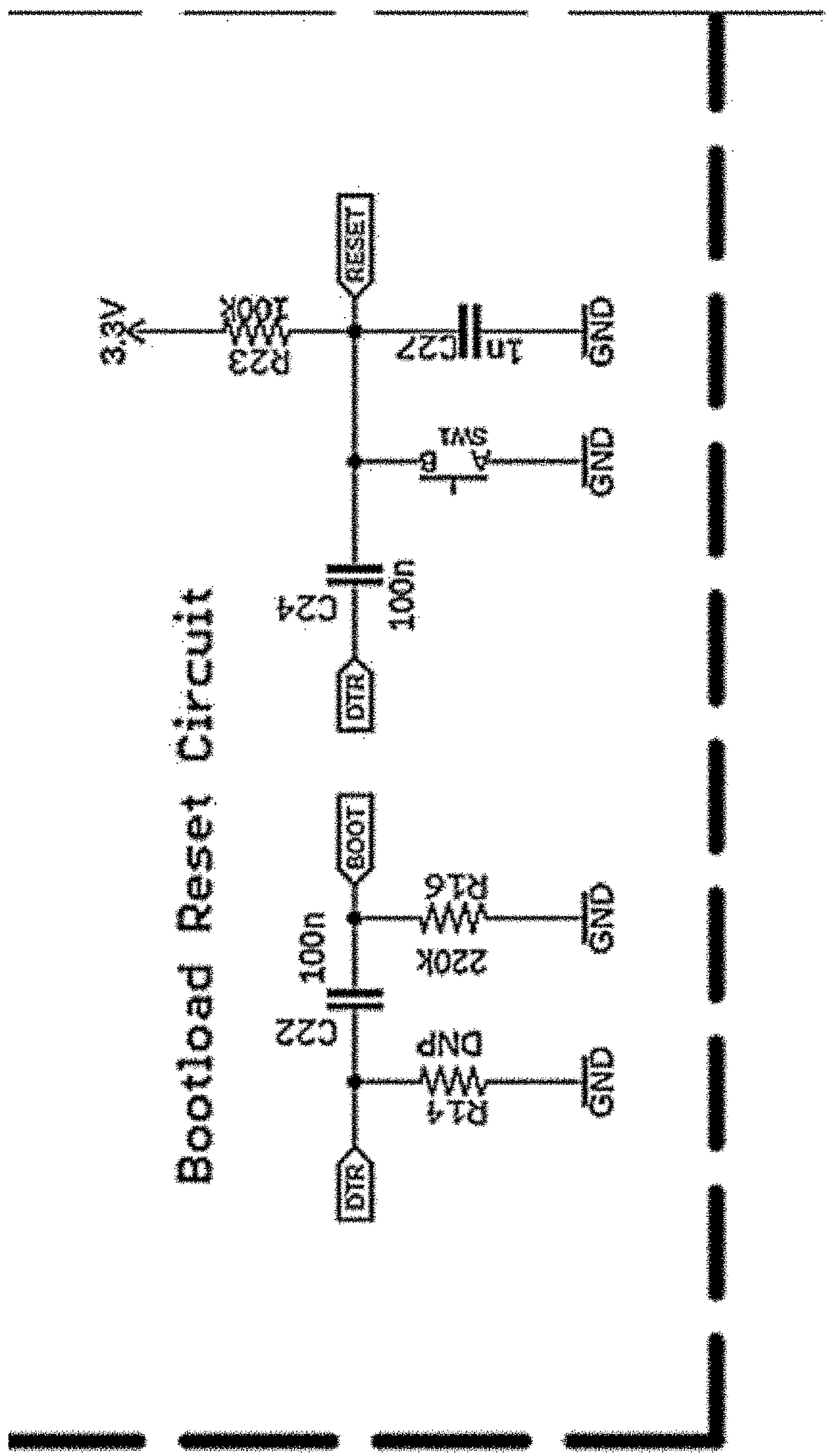

Bootload Reset Circuit
3.3V
R23
100k
RESET
C27
1n
GND
SW1
A
B
GND
C24
100n
DTR
BOOT
R16
220k
GND
C22
100n
R14
DNP
GND
DTR

FIG. 11C

JTAG

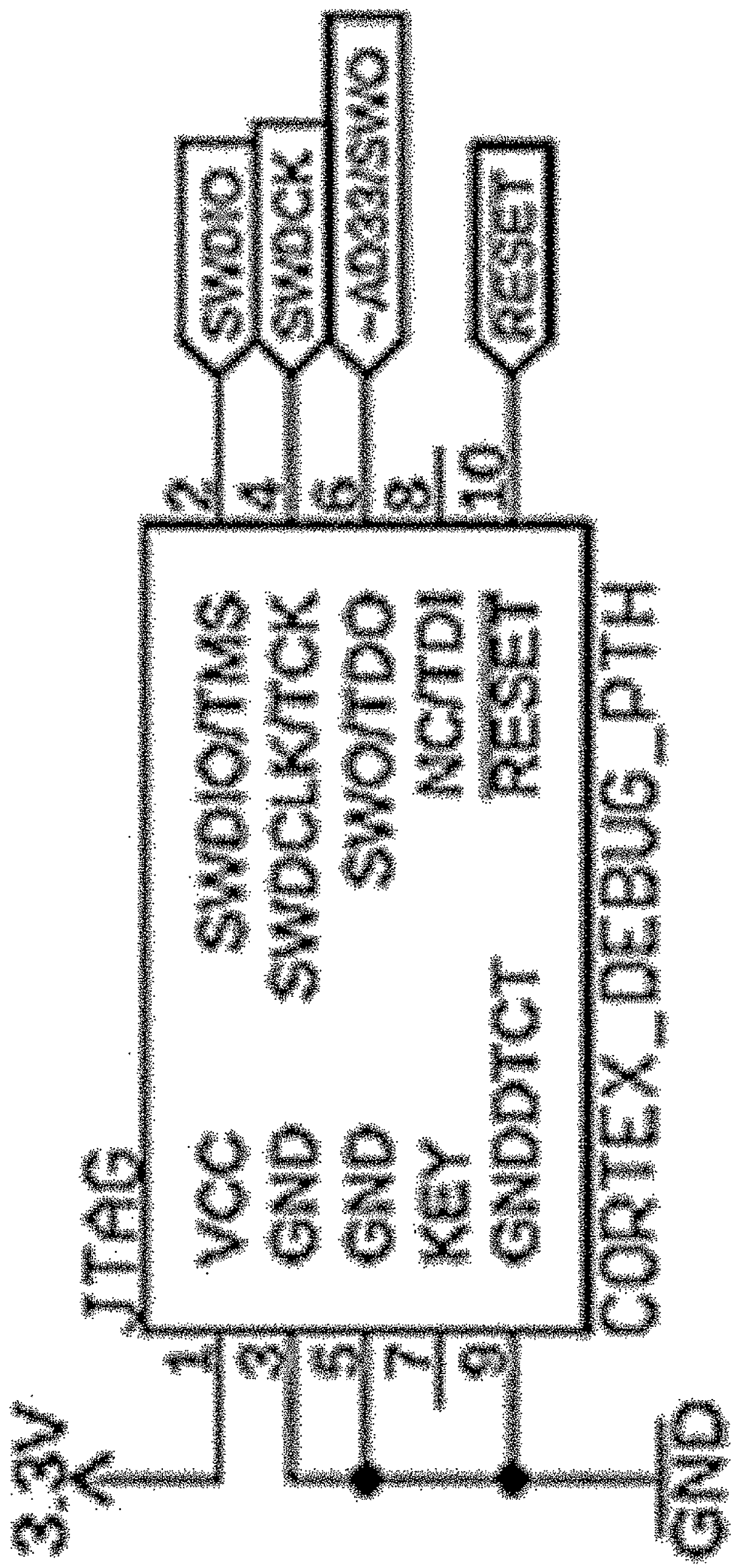

SWDIO
SWDCK
RESET
JTAG
VCC
GND
GND
KEY
GNDDTCT
SWDIO/TMS
SWDCLK/TCK
SWO/TDO
NC/TDI
RESET
CORTEX_DEBUG_PTH
1
2
3
4
5
6
7
8
9
10
3.3V
GND

FIG. 12

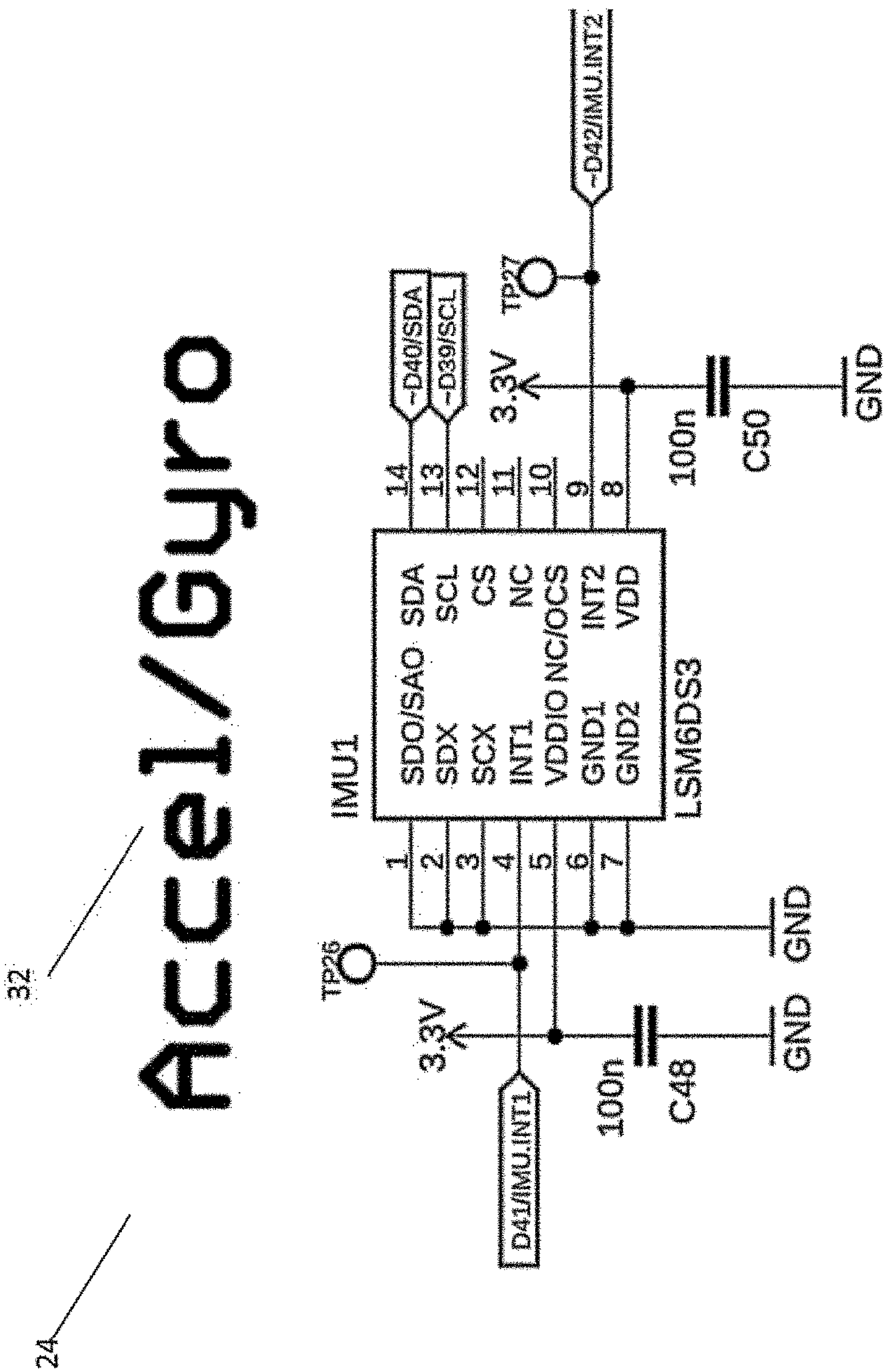
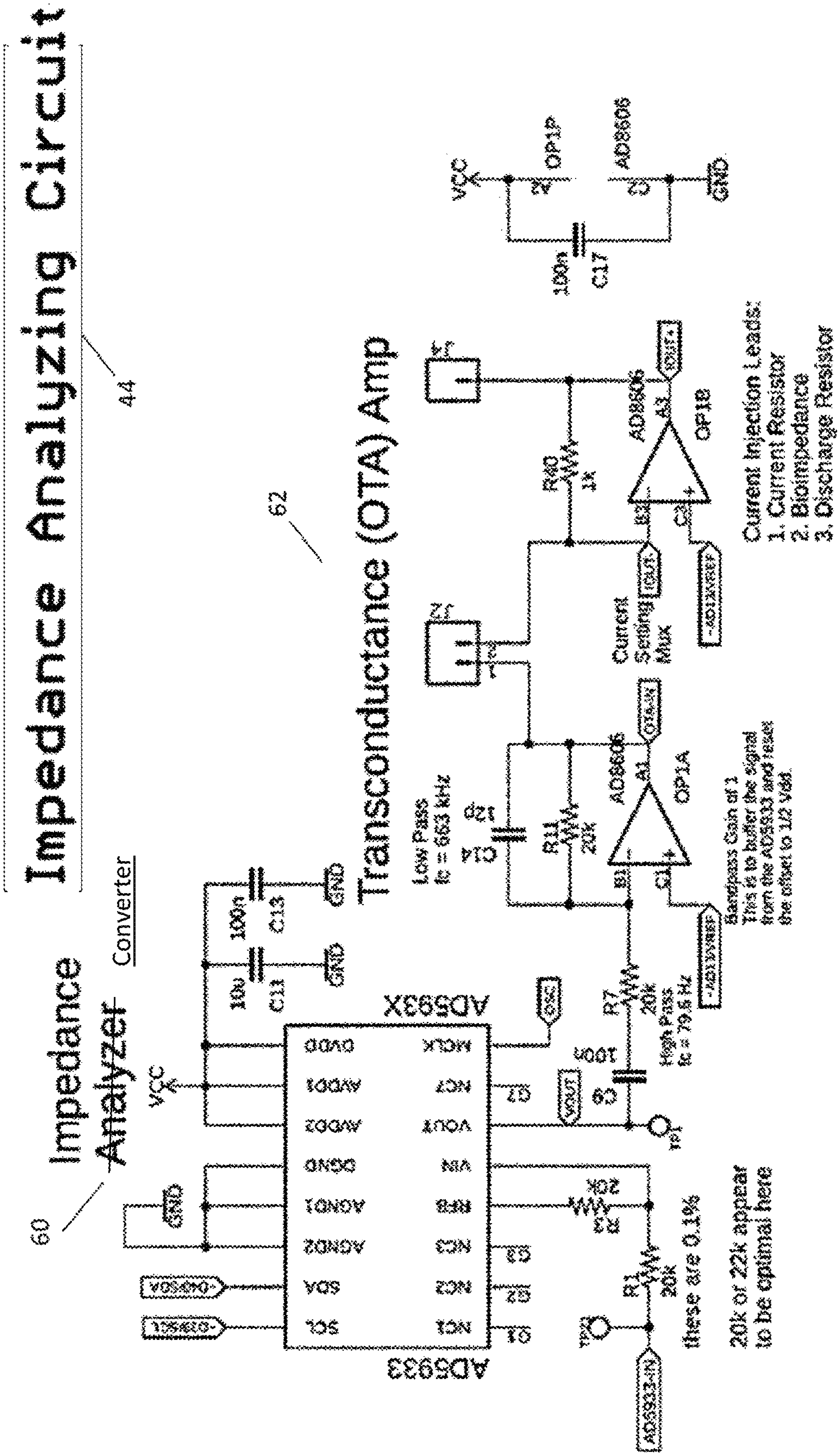

Accel/Gyro
32
24
IMU1
LSM6DS3
SDO/SAO
SDX
SCX
INT1
VDDIO
GND1
GND2
SDA
SCL
CS
NC
NC/OCS
INT2
VDD
1
2
3
4
5
6
7
14
13
12
11
10
9
8
~D40/SDA
~D39/SCL
~D42/IMU.INT2
D41/IMU.INT1
TP26
TP27
3.3V
3.3V
100n
C48
100n
C50
GND
GND
GND

FIG. 13A



Impedance Analyzing Circuit
44
Impedance Analyzer Converter
60
Transconductance (OTA) Amp
62
AD5933
AD593X
Low Pass
fc = 663 kHz
High Pass
fc = 79.6 Hz
Current Setting Mux
Current Injection Leads:
1. Current Resistor
2. Bioimpedance
3. Discharge Resistor
these are 0.1%
20k or 22k appear to be optimal here

FIG. 13B

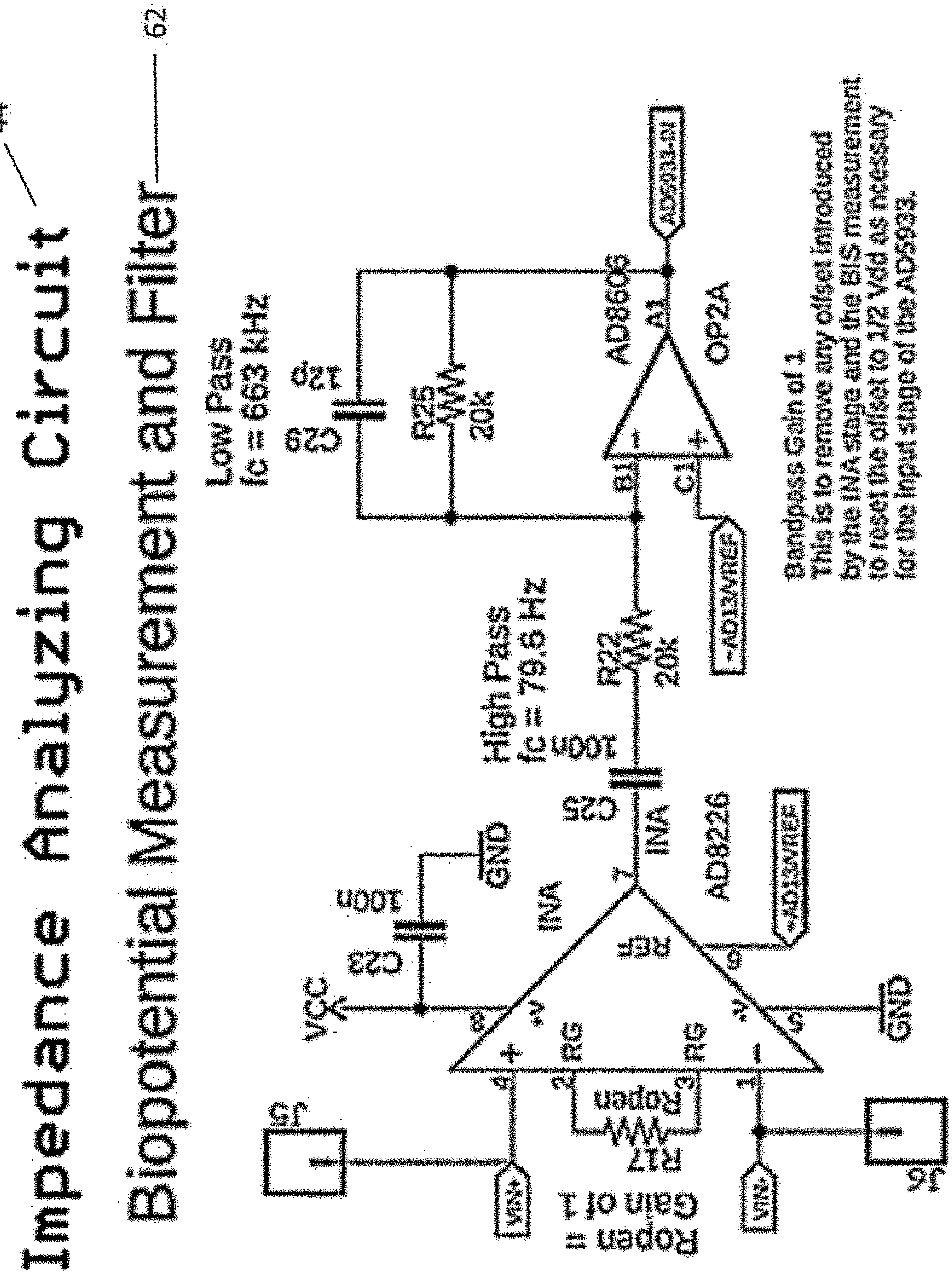
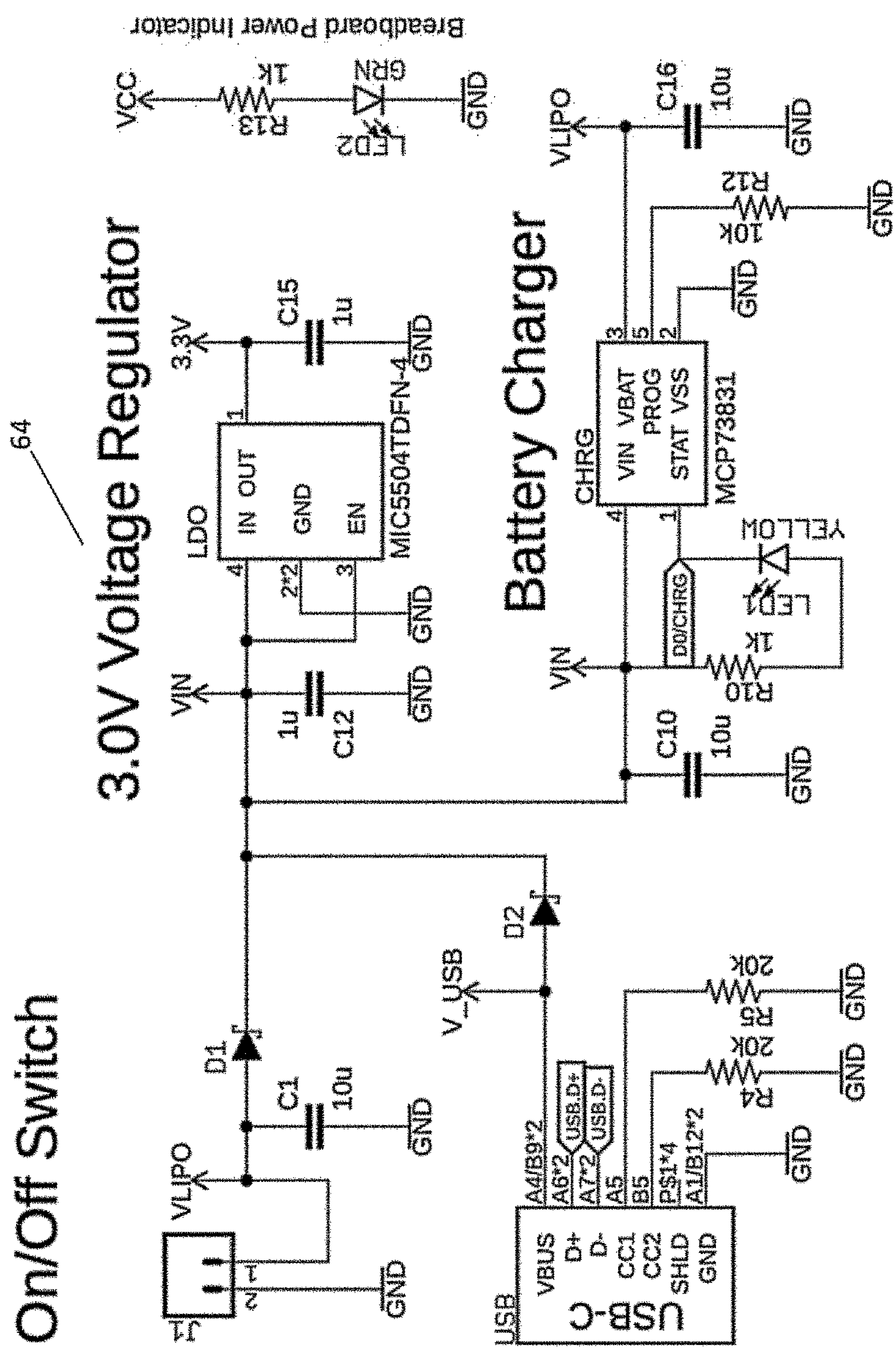

44
Impedance Analyzing Circuit
62
Biopotential Measurement and Filter
Low Pass
fc = 663 kHz
C29
12p
R25
20k
AD8606
A1
B1
C1
OP2A
AD5933-IN
~AD13/VREF
Bandpass Gain of 1.
This is to remove any offset introduced
by the INA stage and the BIS measurement
to reset the offset to 1/2 Vdd as necessary
for the input stage of the AD5933.
High Pass
fc = 79.6 Hz
C25
100n
R22
20k
INA
AD8226
~AD13/VREF
C23
100n
GND
VCC
REF
RG
Ropen
R17
J5
J6
VIN+
VIN-
GND
Ropen =
Gain of 1

FIG. 14A


64
On/Off Switch
J1
VLIPO
GND
D1
C1
10u
3.0V Voltage Regulator
VIN
1u
C12
LDO
IN OUT
GND
EN
MIC5504TDFN-4
3.3V
C15
1u
Battery Charger
CHRG
VIN VBAT
PROG
STAT VSS
MCP73831
D0/CHRG
R10
1K
LED1
YELLOW
R12
10K
C16
10u
C10
Breadboard Power Indicator
VCC
R13
1K
LED2
GRN
V_USB
D2
R5
20K
R4
USB.D+
USB.D-
VBUS
D+
D-
CC1
CC2
SHLD
USB-C
USB

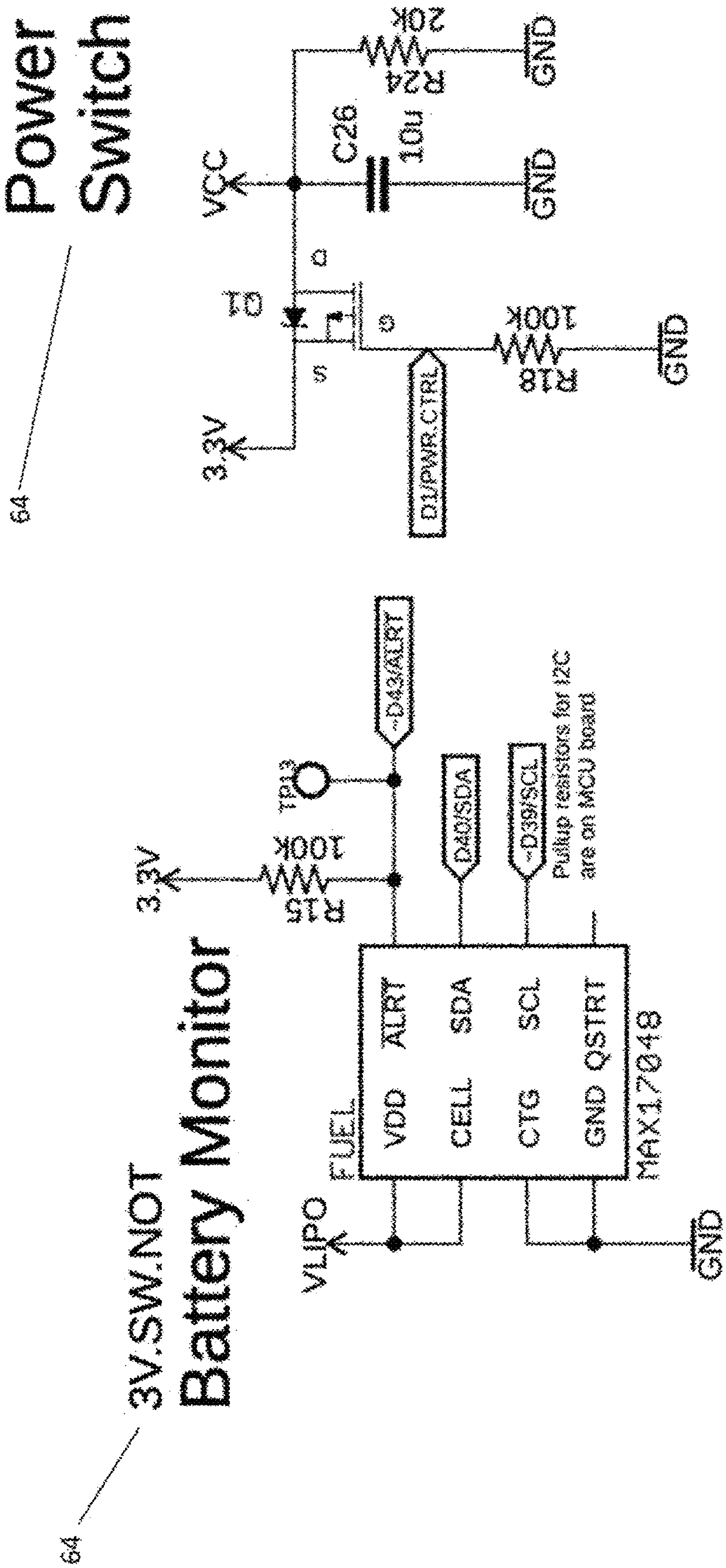

Power Switch
64
VCC
C26
10u
R24
20K
GND
Q1
D
S
G
3.3V
D1/PWR.CTRL
R18
100K
3V.SW.NOT
Battery Monitor
64
VLIPO
FUEL
VDD
CELL
CTG
GND
ALRT
SDA
SCL
QSTRT
MAX17048
R15
100K
TP13
~D43/ALRT
D40/SDA
~D39/SCL
Pullup resistors for I2C are on MCU board

FIG. 14B

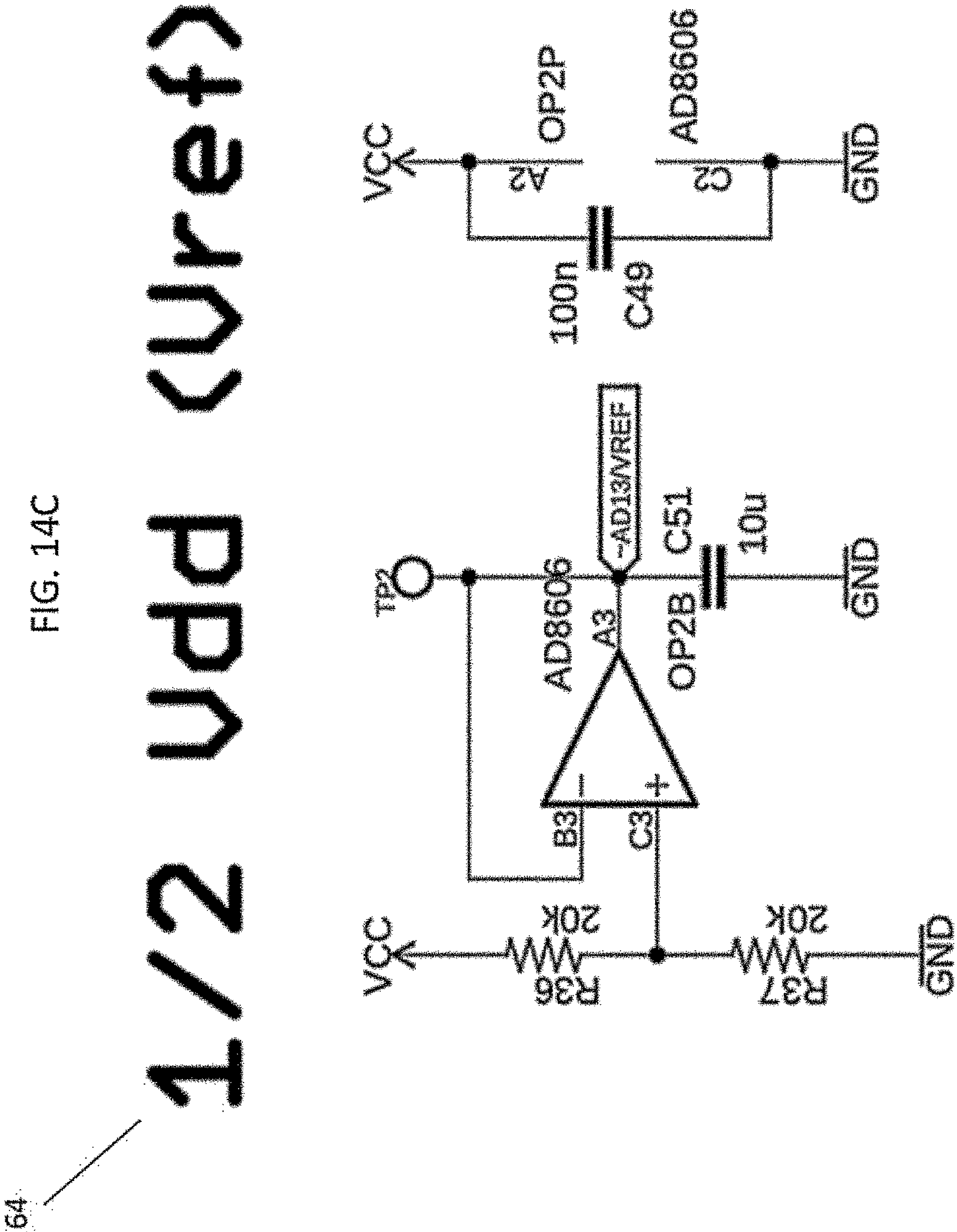

1/2 Vdd (Vref)
VCC
OP2P
AD8606
A2
C2
GND
100n
C49
TP2
AD8606
A3
OP2B
~AD13/VREF
C51
10u
GND
B3
C3
VCC
20K
R36
20K
R37
GND
64

FIG. 14C

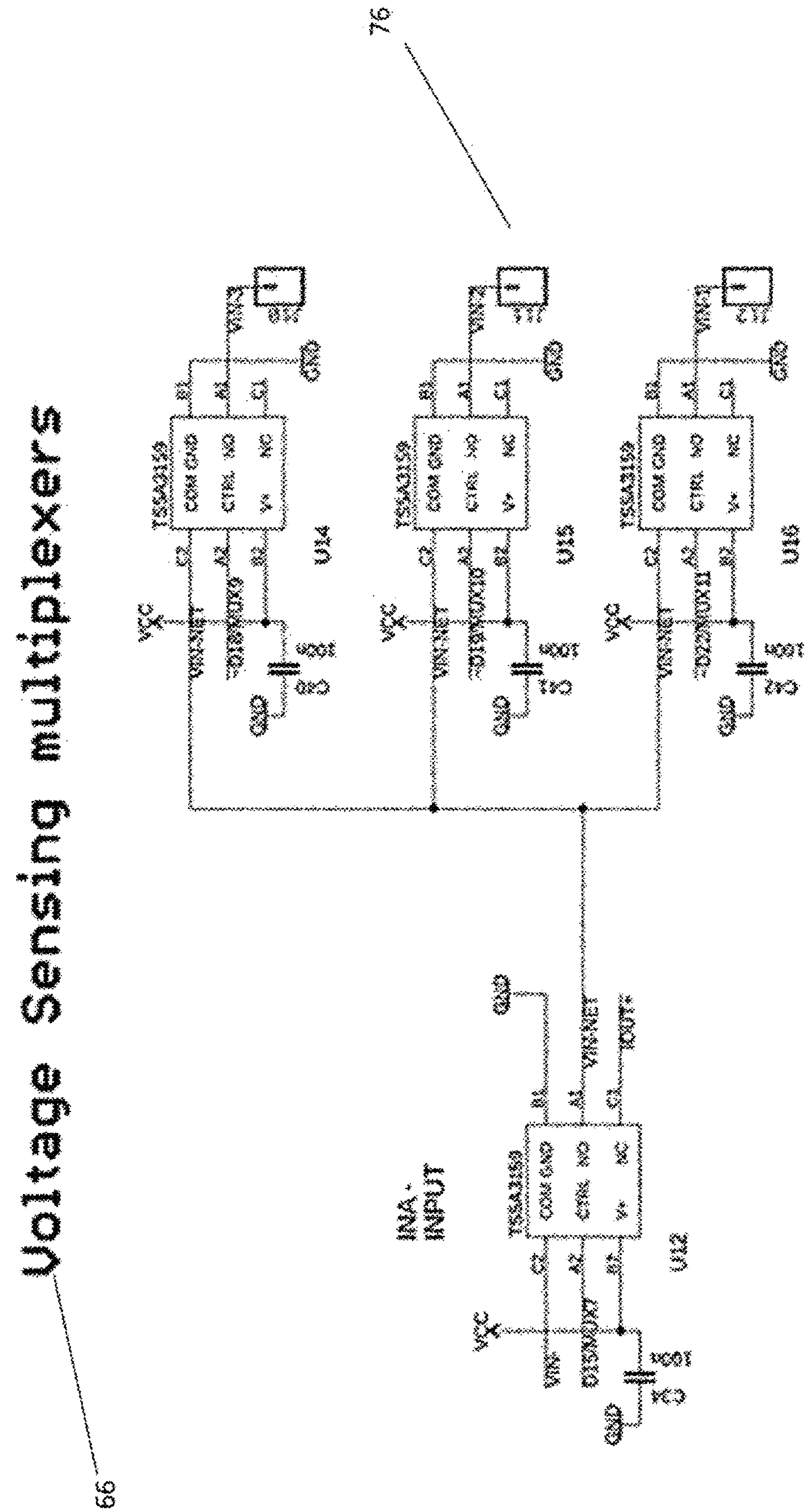

Voltage Sensing multiplexers
66
76
TS5A3159
COM GND
CTRL NO
V+ NC
U12
U14
U15
U16
INA-
INPUT
VIN-NET
GND
VCC
100n

FIG. 15A

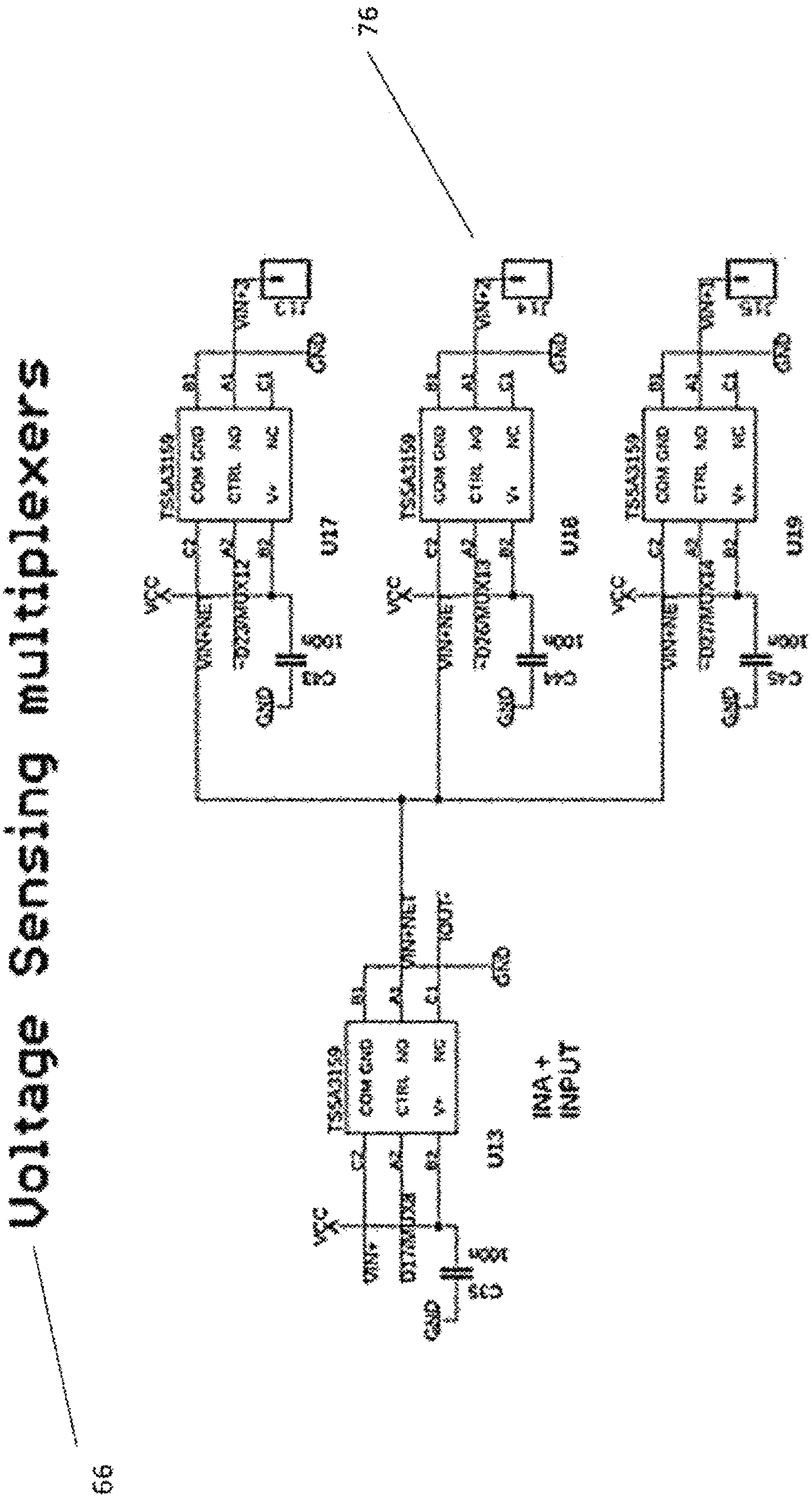

Voltage Sensing multiplexers
66
76
TS5A3159
U13
U17
U18
U19
INA + INPUT
VCC
GND
VIN+NET
COM GND
CTRL NO
V+ NC
100n

FIG. 15B

FIG. 16

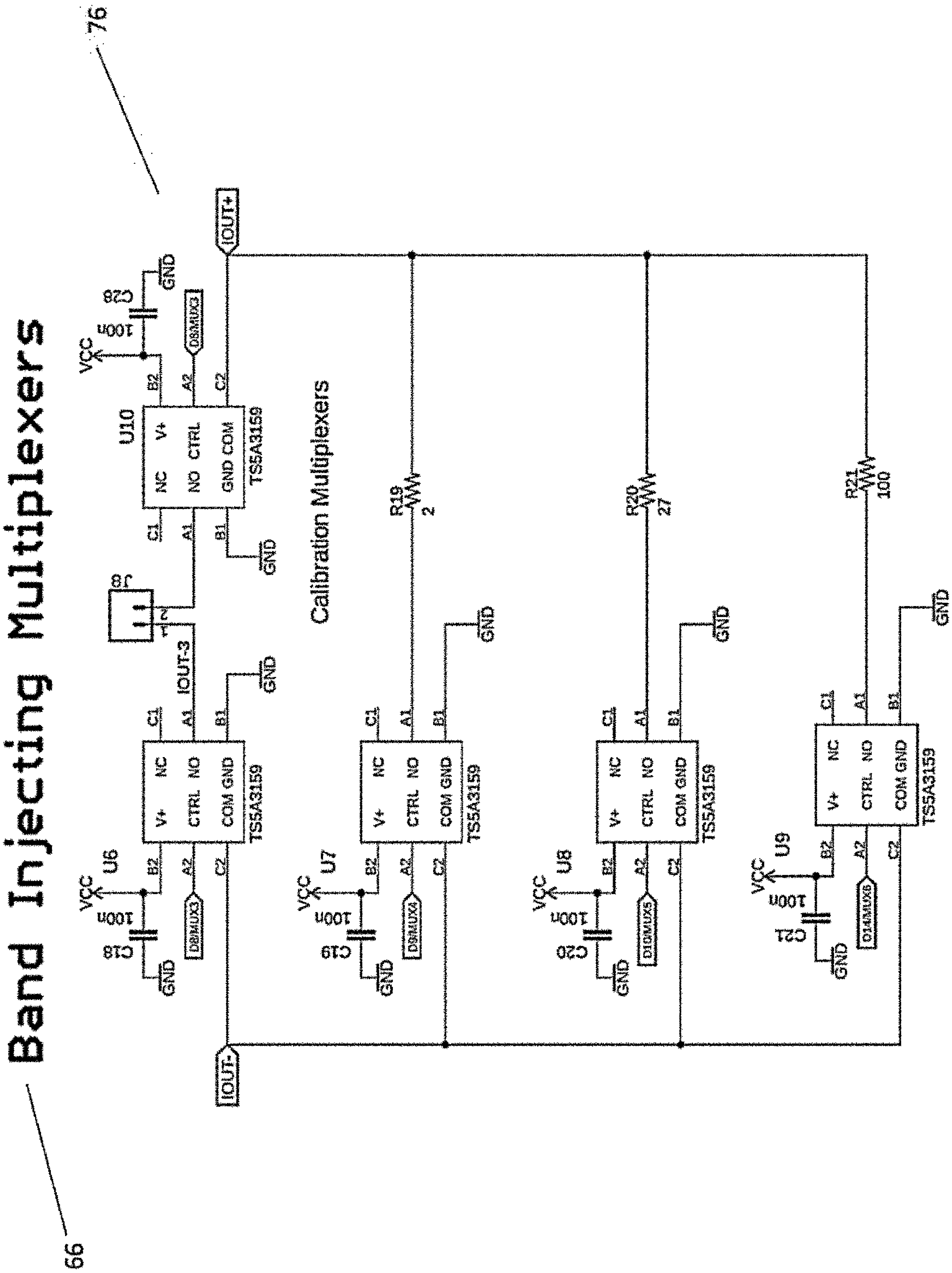
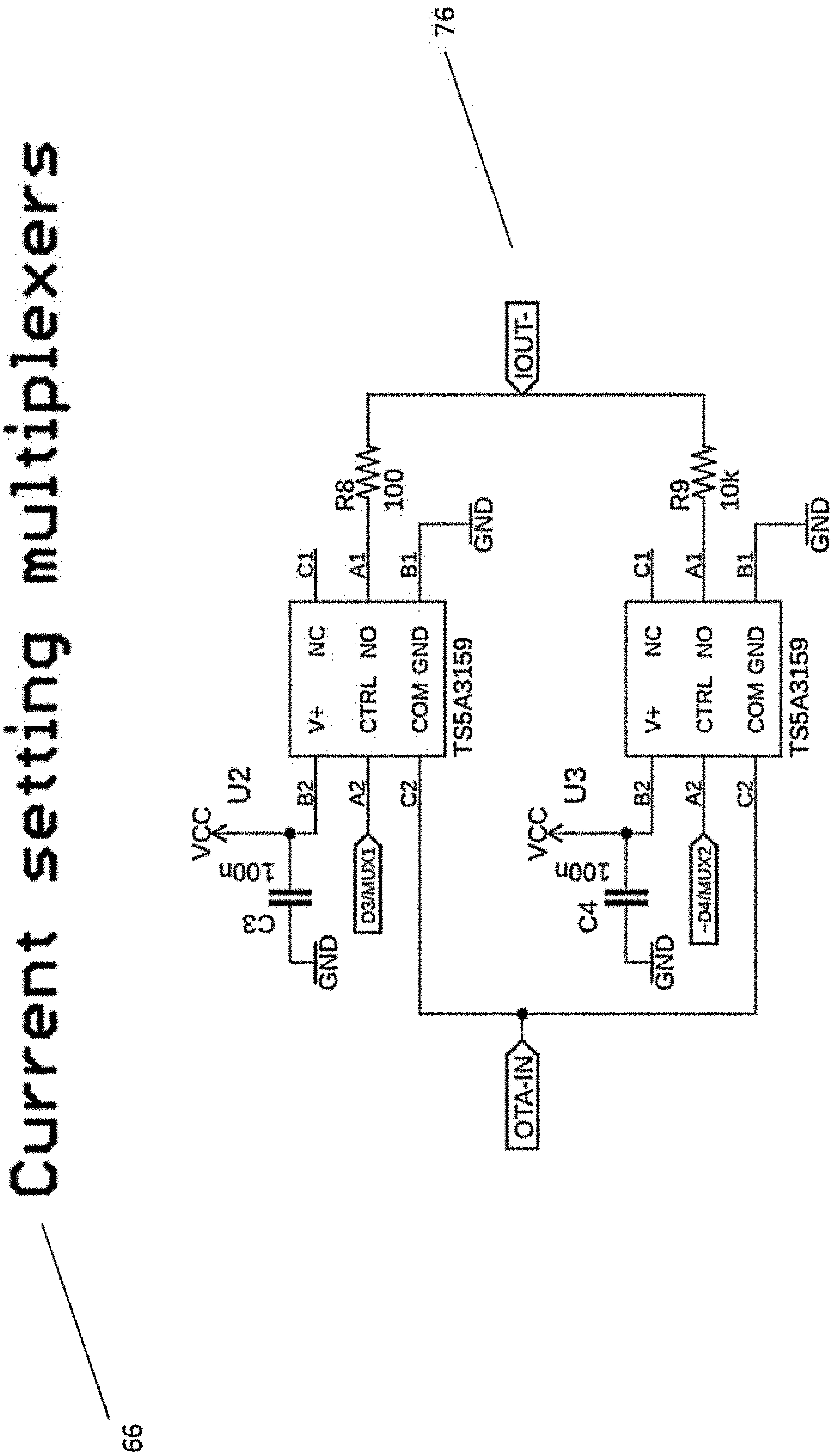

Band Injecting Multiplexers
Calibration Multiplexers
76
66
IOUT+
IOUT-
IOUT-3
J8
U6
U7
U8
U9
U10
TS5A3159
V+
NC
CTRL
NO
COM
GND
VCC
C18
C19
C20
C21
C28
100n
R19
2
R20
27
R21
100
D8/MUX3
D9/MUX4
D10/MUX5
D14/MUX6
A1
A2
B1
B2
C1
C2

FIG. 17


Current setting multiplexers
66
76
IOUT-
R8
100
R9
10k
GND
C1
A1
B1
NC
NO
COM GND
V+
CTRL
TS5A3159
U2
U3
B2
A2
C2
VCC
100n
C3
C4
D3/MUX1
~D4/MUX2
OTA-IN

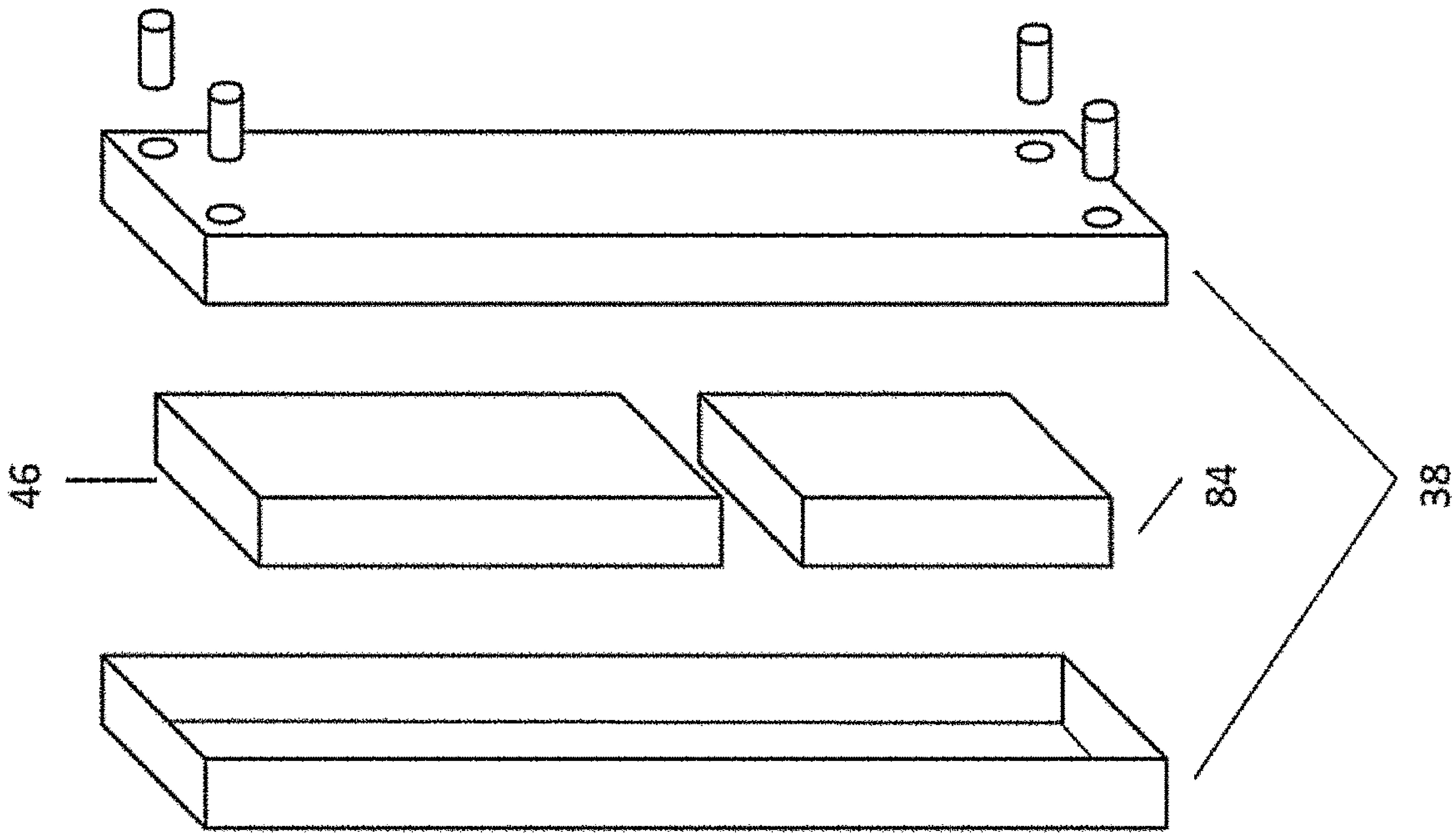


FIG. 18

FIG. 19

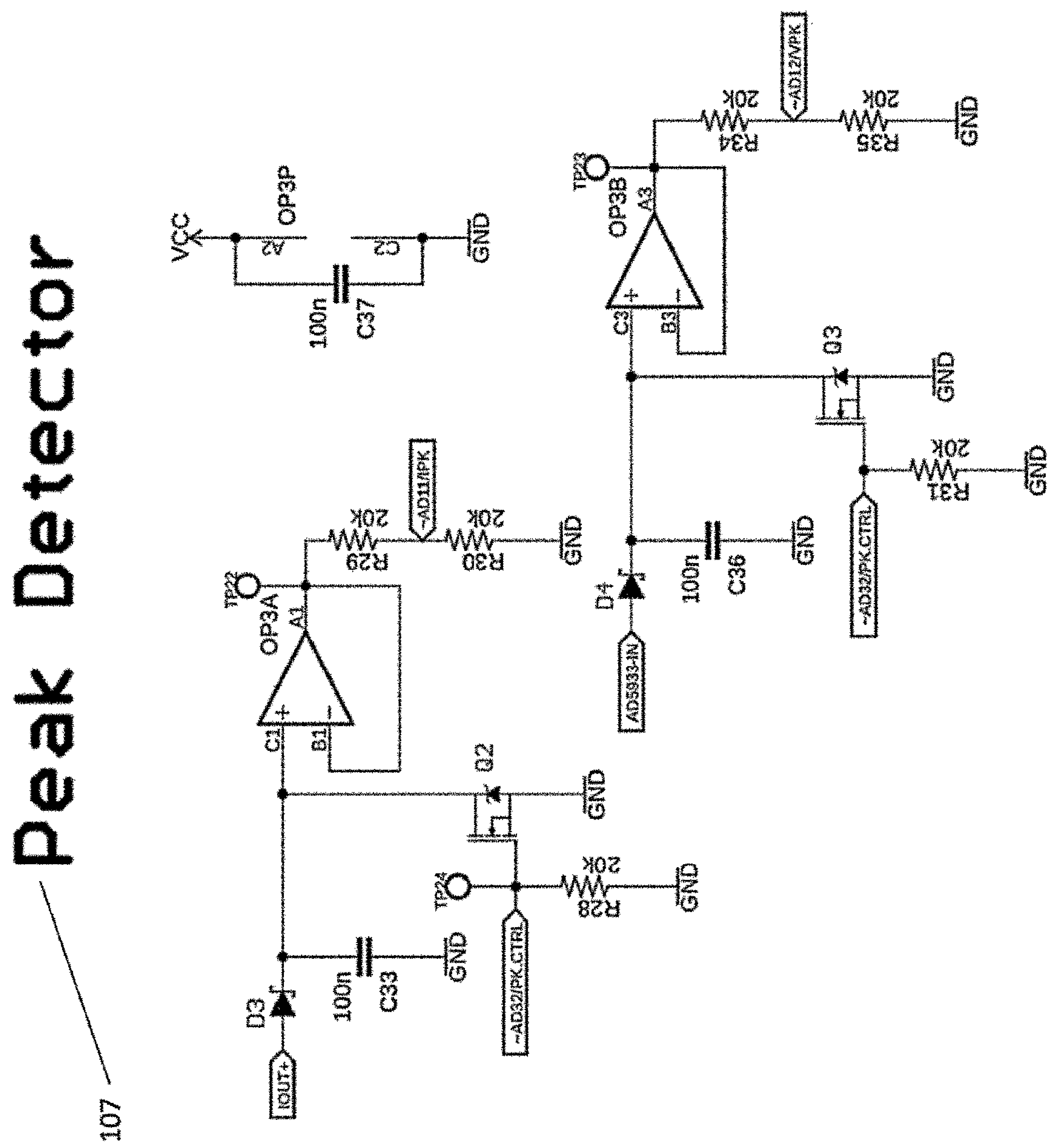

Peak Detector
107
IOUT+
D3
100n
C33
GND
~AD32/PK.CTRL
TP24
R28
20K
Q2
C1
B1
OP3A
A1
TP22
R29
20K
~AD11/IPK
R30
20K
VCC
A2
C2
100n
C37
OP3P
AD5933-IN
D4
C36
Q3
~AD32/PK.CTRL
R31
20K
C3
B3
OP3B
A3
TP23
R34
20K
~AD12/VPK
R35
20K

FIG. 20

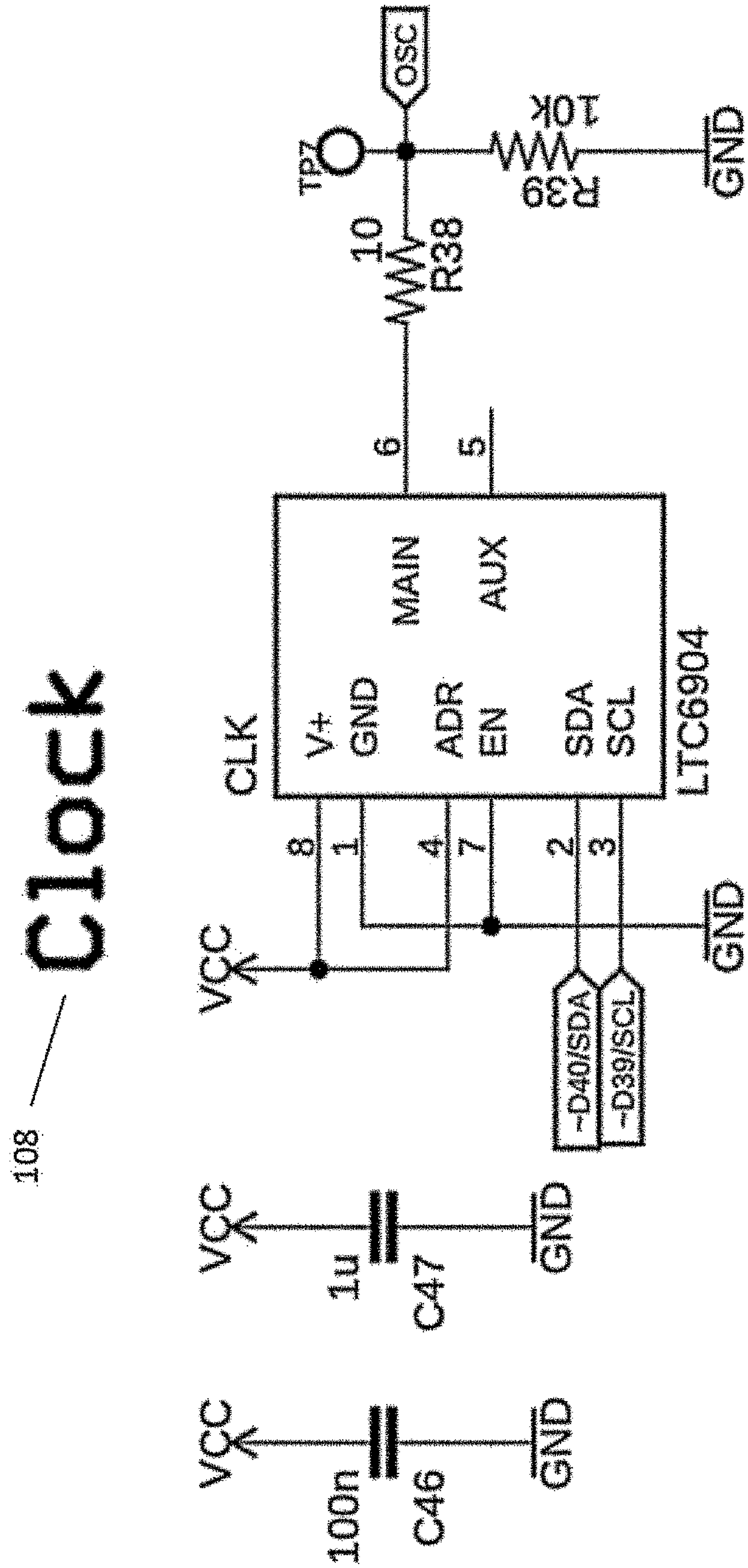

Clock
108
CLK
LTC6904
V+
GND
ADR
EN
SDA
SCL
MAIN
AUX
8
1
4
7
2
3
6
5
VCC
GND
~D40/SDA
~D39/SCL
R38
10
TP7
OSC
R39
10K
C47
1u
C46
100n

FIG. 21

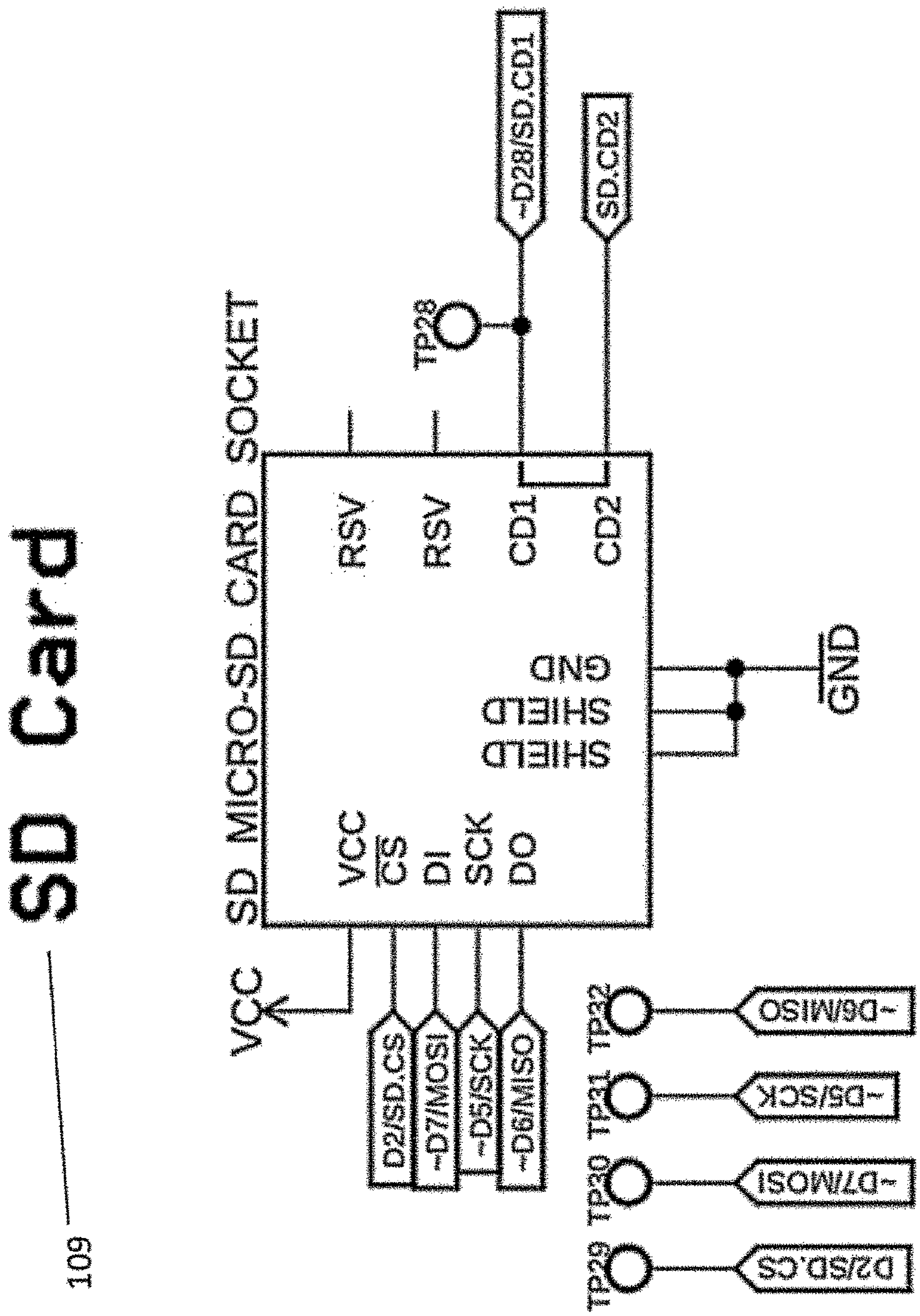
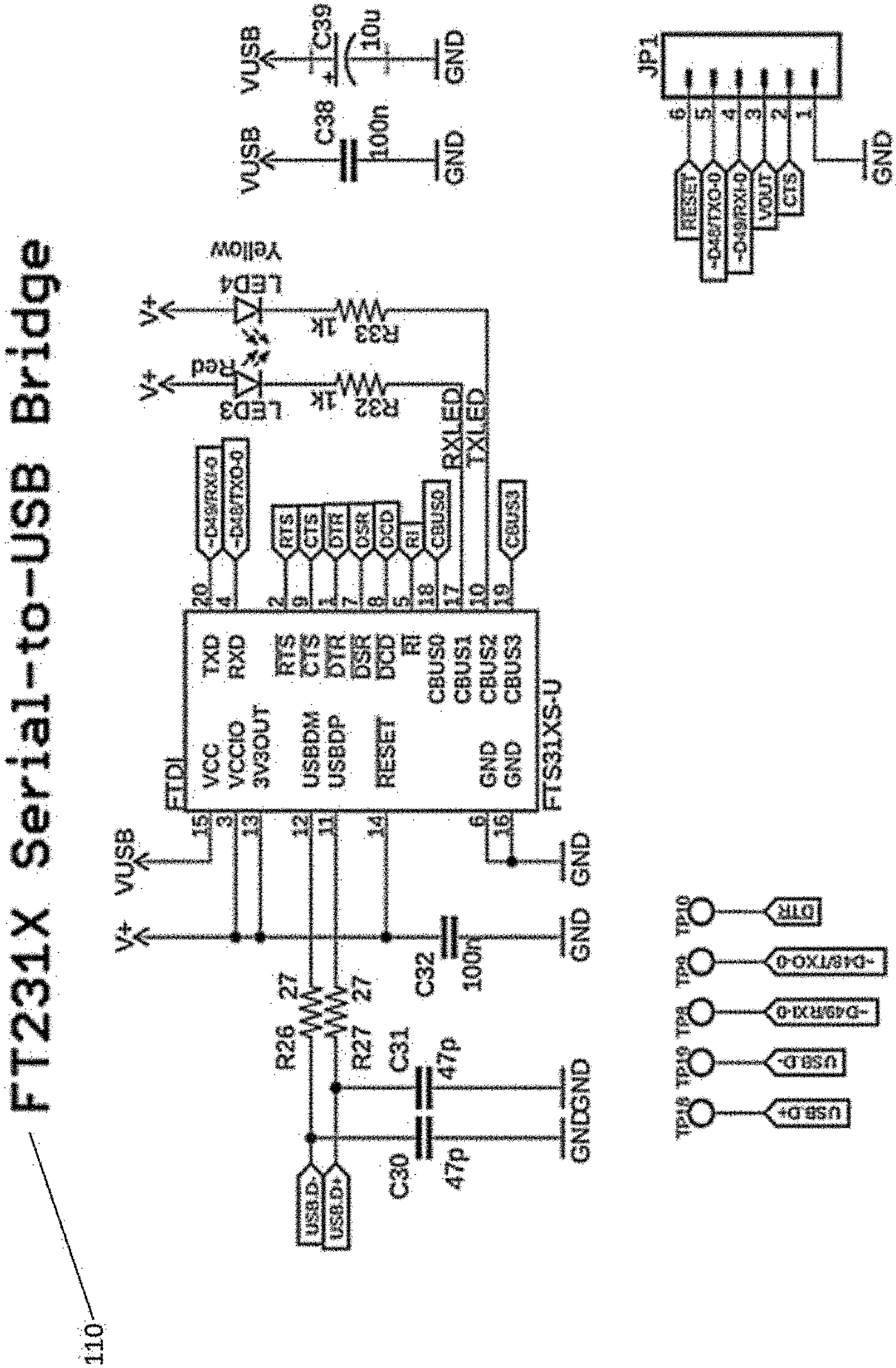

SD Card
109
SD MICRO-SD CARD SOCKET
VCC
CS
DI
SCK
DO
RSV
RSV
CD1
CD2
GND
SHIELD
SHIELD
GND
VCC
D2/SD.CS
~D7/MOSI
~D5/SCK
~D6/MISO
TP28
~D28/SD.CD1
SD.CD2
TP29
TP30
TP31
TP32
D2/SD.CS
~D7/MOSI
~D5/SCK
~D6/MISO

FIG. 22


FT231X Serial-to-USB Bridge
110
FTDI
FTS31XS-U
VCC
VCCIO
3V3OUT
USBDM
USBDP
RESET
GND
GND
TXD
RXD
RTS
CTS
DTR
DSR
DCD
RI
CBUS0
CBUS1
CBUS2
CBUS3
VUSB
V+
GND
R26
R27
27
C30
C31
47p
C32
100n
USB.D-
USB.D+
RXLED
TXLED
R32
R33
1k
LED3
LED4
Red
Yellow
C38
100n
C39
10u
JP1
RESET
VOUT
CTS
TP10
TP18
DTR
USB D-
USB D+

MATTER OF MANUFACTURE OF COMPRESSION LEGGING SYSTEM AND ASSOCIATED USES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a PCT Bypass continuation application of international PCT application number PCT/US20/20871, filed Mar. 4, 2020 which claimed benefit of U.S. provisional application No. 62/813,887, filed Mar. 5, 2019, the subject matter of each of the above referenced disclosures is expressly incorporated by reference herein.

a PCT international patent application of and claims the priority of U.S. provisional patent application Ser. No. 62/856,410, titled "IMPEDANCE BASED COMPRESSION LEGGING SYSTEM" filed on Jun. 3, 2019, U.S. provisional patent application Ser. No. 62/813,887, titled "COMPRESSION LEGGING SYSTEM" filed on Mar. 5, 2019 and incorporates the subject matter of each thereof in its entirety.

This application incorporates the subject matter of U.S. provisional patent application Ser. No. 62/405,442 filed on Oct. 7, 2016, in its entirety.

FIELD OF THE INVENTION

The present disclosure relates to the matter of construction and use of a compression legging system that combines an impedance monitor, a patient activity monitor, medical compression legging material, and a mobile application for detection of recurrent disease. The compression legging system is intended for the detection of human diseases including a group of congestive heart failure (CHF), post-thrombotic syndrome (PTS), deep vein thrombosis (DVT), venous injury, venous stasis (Virchow's triad of hypercoagulability), pulmonary emboli (PE), inflammation and swelling of the extremities.

BACKGROUND OF THE INVENTION

Post-thrombotic syndrome (PTS) affects 750,000 individuals in the U.S. and develops after deep vein thrombosis (DVT damages valves in the deep venous system. History of DVT, venous injury, and venous stasis (Virchow's triad of hypercoagulability) place PTC patients at high risk of recurrent DVT and pulmonary emboli (PE) (cumulative incidence of recurrent DVT in this population is approximately 20%).

Symptomatic DVT accounts for most PE, and if not treated within three months, has a 15% mortality rate. This mortality rate can be reduced to 4% if the DVT is detected successfully at an earlier stage. Therefore, detection of symptomatic, recurrent DVT in PTS patients may allow for treatment-based reduction in the fatality caused by PE in this population.

PTS patients are commonly prescribed compression stockings to prevent recurrent DVT, prevent venous ulceration, and reduce leg swelling. Compression stockings, compression leggings, and compression sleeves are produced by many manufacturers. These compression garments can be outfitted with several textile-based electrodes, for example textile electrodes for electrocardiogram (EKG) monitoring created by Textronix, Inc. Several commercially-available bio-impedance body monitors perform similar measurements and analyses of hydration and similar body properties. These include monitors sold by Tanita Corporation, for example Ironman Body Composition Monitors,

ImpediMed for example SOZO system which has been FDA-cleared for detection of lymphedema, and InBody USA, for example InBody 770, marketed for detection of lymphedema.

The Wells Criteria are a well-established clinical assessment that determines the likelihood that a patient has DVT, where the likelihood of DVT correlates linearly with a patient's Wells Score.

TABLE 1

Wells Criteria for the likelihood of DVT: A patient's Wells Score is the sum of their scores for each Wells Criterion. −2 to 0: Low probability; 1 to 2 points: Moderate probability; 3 to 8 points: High probability [34]. "Given" - all PTS patients have a history of DVT.

Wells Criterion	Score	Proposed Method
Active cancer (within past 6 months)	1	Section 3.2.4
Paralysis, paresis, or recent cast immobilization	1	Section 3.2.2 & 3.2.4
Recently bedridden for 3+ days or major surgery w/in 12 weeks	1	Section 3.2.2 & 3.2.4
Localized tenderness	1	Section 3.2.4
Entire leg swelling	1	Section 3.2.1
Calf swelling at least 3 cm larger than asymptomatic leg	1	Section 3.2.1
Pitting edema confined to symptomatic leg	1	Section 3.2.4
Collateral superficial veins (non-varicose)	1	Section 3.2.4
Previous documented DVT	1	Given
Alternative diagnosis at least as likely as DVT	−2	Section 3.2.4

A Wells Score of <1 rules out DVT with a sensitivity and negative predictive value of 100%. Overall, the Wells Score can predict DVT with a sensitivity of 77%-98%, a specificity of 37%-58%, a negative predictive value of 81-98%, and a positive predictive value of 14.2-63%, making the criteria a robust determination of patient DVT.

As patients with PTS are at high risk for recurrent DVT, and recurrent DVT is in turn an important risk factor for fatal PE, it is critical that PTS patients quickly recognize recurrent DVT and seek medical attention.

Bio-impedance spectroscopy (BIS) is a well-established, reliable method to determine the level of swelling in a segment of tissue. It gives 96%-100% sensitivity and 96% specificity in detecting a variety of clinical manifestations of swelling and outperforms circumferential and volumetric leg measurements in sensitivity and specificity. BIS works by injecting multiple frequencies of alternating current (AC) into a volume of tissue and measuring the impedance of the tissue at each frequency.

Accumulation of fluid in tissue, such as in PTS-induced swelling, alters the tissue's impedance spectrum and can therefore be detected with BIS. In the tetrapolar electrode configuration (TEC), four electrodes are used for BIS: two current-injecting electrodes and two voltage-sensing electrodes. TEC minimizes the impact of variable skin-electrode contact impedances, polarization effects, and movement artifacts, since the voltage-sensing electrodes draw negligible current.

SUMMARY OF THE INVENTION

The present disclosure comprises a compression legging system that combines a swelling monitor, a patient activity monitor, a medical compression legging, and a mobile application. The compression legging system intended to help patients detect recurrent DVT (and associated symptoms) to seek medical attention prior to the development of

PE. The application of the compression legging system will simultaneously reduce swelling and prevent DVT via compression therapy.

The proposed methodology is the first attempt to bring scientifically-validated clinical evaluations of DVT to the home environment. Rather than mandating patients return to the clinic for re-evaluation when they subjectively suspect recurrent DVT, the proposed smart compression legging and accompanying mobile application may utilize a well-established, objective, and scientifically-validated clinical evaluation (the Wells Score) to determine the likelihood that a patient has developed DVT. The system does not require a compression user to locate and use a separate impedance-measuring device to track their impedance and derived measurements. The system does not require a physician or other person to meet with the user to take impedance measurements or to view impedance measurements or derivative measurements. Consequently, this strategy has potential to substantially reduce the incidence and mortality of PE in the PTS patient population.

The proposed smart compression legging and paired mobile application may utilize a combination of non-invasive sensors and user-answered questions to generate a Wells Score for each patient. PTS patients must differentiate between recurrent DVT and the non-DVT-associated episodic and chronic pain and swelling they often experience. PTS patients are generally told to rest and elevate their legs for 24 hours before seeking medical care for leg pain and swelling. If elevation does not reduce these symptoms, the patient is then screened for DVT. Consequently, if a patient receives a moderate or high Wells Score, the proposed device may notify the patient via the mobile app that they should carefully monitor, elevate, and rest their leg for the next 24 hours. The proposed device may then analyze the patient's Wells Score during such elevation and may prompt the patient to seek medical care for potential DVT if no improvement occurs within 24 hours. In this manner, the proposed smart compression legging may help PTS patients detect recurrent DVT through a well-established clinical evaluation and seek medical attention quickly before the development of PE while simultaneously reducing swelling and preventing DVT via compression prophylaxis.

In illustrative embodiments, the present invention comprises a compression garment, a wearable sensor network, and an application. Examples of detailed applications are described below.

In illustrative embodiments, the present invention discloses the manufacture of a compression legging system.

In a further aspect of the disclosure, use of a compression legging system to help PTS patients detect recurrent DVT.

In a further aspect of the disclosure, the compression legging system may be adapted for use of detecting diseases other than PTS, such as congestive heart failure, and lymphedema, as well as post-operative care.

In a further aspect of the disclosure, the legging's ability to aid in the detection of DVT, lower cost, and design considerations for comfort, aesthetic, and ease of use make it significantly superior to all competitors.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A illustrates a back view of the smart compression legging system that comprises compression material containing the following components: i) compression material with fabric traces, ii) central hardware housing the monitor, iii) current-injecting electrodes, and iv) voltage sensing electrodes. Features of exterior are shown; fabric traces and the central hardware housing the monitor.

FIG. **1**B illustrates a front view of the smart compression legging system that comprises compression material containing the following components: i) compression material with fabric traces, ii) central hardware housing the monitor, iii) current-injecting electrodes, and iv) voltage sensing electrodes. Features of exterior are shown; fabric traces and the central hardware housing the monitor.

FIG. **1**C illustrates a side view of the smart compression legging system that comprises compression material containing the following components: i) compression material with fabric traces, ii) central hardware housing the monitor, iii) current-injecting electrodes, and iv) voltage sensing electrodes. Features of exterior are shown; fabric traces and the central hardware housing the monitor.

FIG. **2** demonstrates the difference in impedance in the leg due to activity and position. The compression legging system electrodes and hardware could detect and transmit frequency from a human subject while raising and lowering the leg. Points are the mean±95% CI of 12 frequency readings (n=12) in five human subjects (n=5) over a range of frequencies (5,000-100,000 Hz). Statistically significant differences in bio-impedance between leg raised versus leg resting down could be detected in subjects wearing the compression legging system.

FIG. **3**A illustrates a back view of the smart compression legging system that comprises compression material containing the following components: i) compression material with fabric traces, ii) central hardware housing the monitor, iii) current-injecting electrodes, and iv) voltage sensing electrodes. Features of the interior are shown: current-injecting electrodes and voltage sensing electrodes.

FIG. **3**B illustrates a side view of the smart compression legging system that comprises compression material containing the following components: i) compression material with fabric traces, ii) central hardware housing the monitor, iii) current-injecting electrodes, and iv) voltage sensing electrodes. Features of the interior are shown: current-injecting electrodes and voltage sensing electrodes.

FIG. **4** illustrates a linear neural network that could be utilized to classify four tasks: 1) standing, 2) sitting, 3) sleeping, and 4) elevating the leg. Accel is accelerometer. Gyro is gyroscope.

FIG. **5**A shows the training loss of the compression legging system for the artificial neural network (ANN) by training epoch.

FIG. **5**B shows the validation loss of the compression legging system for the artificial neural network (ANN) by training epoch.

FIG. **6**A shows the compression legging system total neural network accuracy by epoch. Accuracy refers to a percent scale (100% accuracy meaning proper detection of task). The compression legging system could determine each of four classes of tasks: sitting, standing, sleeping, and elevating the leg, after training the neural network, with 80-100% accuracy.

FIG. **6**B shows the compression legging system total neural network accuracy and task (class) accuracies by epoch. Accuracy refers to a percent scale (100% accuracy meaning proper detection of task). The compression legging system could determine each of four classes of tasks: sitting, standing, sleeping, and elevating the leg, after training the neural network, with 80-100% accuracy.

FIG. **7** illustrates a wearable sensor network (WSN) including 5 sensor units (SUs) (circles), 3 microcontroller units (MCUs) (gray squares) and connecting flat wires (lines).

FIG. **8** illustrates the architecture of Long Short-Term Memory Deep ("LSTM") where X represents the bio-impedance inputs from each sensor unit (SU), Y represents the output of the network for a given sample, and the blank box represents the neural network.

FIG. **9** illustrates the central hardware flowchart. Impedance and user activity are saved and transmitted to the mobile application device.

FIG. **10** illustrates the mobile application flowchart.

FIG. **11**A illustrates a microcontroller.

FIG. **11**B illustrates a bootload reset circuit.

FIG. **11**C illustrates a Joint Test Action Group (JTAG) interface.

FIG. **12** illustrates an accelerator or gyroscope.

FIG. **13**A illustrates an impedance analyzing circuit.

FIG. **13**B illustrates an impedance analyzing circuit and biopotential measurement and filter.

FIG. **14**A illustrates an on/off switch, voltage regulator and battery charger.

FIG. **14**B illustrates a battery monitor and power switch.

FIG. **14**C illustrates a voltage supply (Vdd) and voltage reference (Vref).

FIG. **15**A illustrates a voltage sensing multiplexer.

FIG. **15**B illustrates a voltage sensing multiplexer.

FIG. **16** illustrates a band injecting multiplexer.

FIG. **17** illustrates a current sensing multiplexer.

FIG. **18** illustrates central hardware with battery in an enclosure.

FIG. **19** illustrates a peak detector.

FIG. **20** illustrates a clock.

FIG. **21** illustrates a ScanDisk (SD) card.

FIG. **22** illustrates a FT231X Serial-to-USB Bridge.

DETAILED DESCRIPTION OF THE INVENTION

The present disclosure relates to, inter alia, a novel compression legging system which functions as a real-time bio-impedance and activity monitor for detection of swelling in the extremities relevant to several human diseases. Likewise, methods for manufacture and utility of such a compression legging system in the detection and/or prevention of human disease conditions are disclosed herein. The embodiments disclosed herein are not intended to be exhaustive.

The definitions of certain terms as used in this specification are provided below. Unless defined otherwise, all technical and scientific terms used herein generally have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. As used in this specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the content clearly dictates otherwise. For example, reference to "a system" includes a combination of two or more components herein, and the like.

Terminology

As used herein, "real-time" refers to the period describing the use of the compression system—i.e. while worn.

As used herein, "computation time" refers to the ability of the compression system hardware to collect, analyze, and transmit information within real-time.

As used herein, "classification accuracy" refers to the ability of the compression system hardware described to collect, analyze, segment, and transmit information concerning specific movements of an individual while wearing the compression system.

As used herein, "segmentation accuracy" refers to the accuracy of the compression system hardware to detect, extract, and transmit various movements within a signal.

Overview

The disclosed system comprises a combination of three functional components: a compression garment, a wearable sensor network, and an application. A compression garment could be any skin-contacting, or near-skin, garment (e.g. waist high stockings, knee high stockings, pantyhose, compression sleeve, headband). In illustrative embodiments described herein, the present disclosure refers to the use of a compression system applied to the leg, but this device could be utilized on the arm or any other portion of the body where these garments could be worn.

The disclosed system utilizes dry textile electrodes for tetrapolar electrode configuration (TEC). These electrodes are applied to the skin at a pressure of 15-40 mmHg, which is known to significantly decrease skin-electrode contact impedance.

The system in the smart compression legging is depicted in FIG. **1**. A circular current-injecting band electrode **80** lies on each ankle **12** and each upper thigh **14**. Five voltage-sensing electrodes **78** lie on each leg **16** between each pair of current-injecting band electrodes **78**. A multiplexor may sequentially alternate which pair of voltage-sensing electrodes **80** is activated to enable segmental impedance analysis of each leg **16**. This monitor may also detect swelling of the entire leg according to the Wells Criterion Scoring (Table 1).

As used herein, the term "composition" refers to a product with specified ingredients in the specified amounts, as well as any product which results, directly or indirectly, from combination of the specified ingredients in the specified amounts.

The system **20** can take bio-impedance measurements in real-time, while a user **22** (FIG. **7**) performs activities. The system **20** does not require a user **22** to remain unmoving. This is the result of the incorporation of accelerometer ("accel")-gyroscope ("gyro") units into the system. The system **20** uses accelerometers **24** and an artificial neural network (ANN) **26** to distinguish between several classes of clinically-relevant patient activity, including sitting, standing, sleeping and elevating the leg (FIG. **4**). An ANN is created to accurately detect and classify five simple movement and three complex movements using data from five AGMs on the wearable sensor network (WSN) **28**. To achieve this, a Recurrent Neural Network (RNN) **30** may be utilized (see FIG. **8**). RNNs **30** have shown promising performances in areas such as speech recognition, label generation, handwriting recognition, and language modeling. In recent years, RNNs **30** have been utilized successfully to classify many complex and simple tasks such as running, sitting, standing, jumping, and walking left, right, forwards, and backwards with accuracies exceeding 90%. This accuracy is commonly attributed to RNNs **30** ability to exploit contextual and temporal information within variable length signals. In this manner, the proposed RNN **30** may be able to detect the larger context of a task, such as how a user **22** repetitively swings their arms while running. Using all 30 individual signals (6 samples from each of the 5 SUs **32**) as input, the RNN **30** may classify across a 5 second snapshots in time. This methodology may allow the passing window to observe the activity of a user **22** within a larger frame of reference. The network **34** developed may be evaluated across three metrics:

To properly evaluate potential RNNs **30**, the networks **34** may be trained and evaluated using open source datasets, such as the University of Southern California human activity dataset (USC-HAD). Multiple architectures, such as Long Short-Term Memory Deep Recurrent Neural Networks (LSTM-DRNN) and LSTM Convolutional neural networks (LSTM CNN) may be evaluated.

The wearable sensor network (WSN) **28** comprises the circuitry utilized to provide the functionality of the smart compression garment **36** and the enclosures **38** utilized to join the sensors **40** to the smart compression garment **36**. The circuitry of the WSN **28** comprises an accelerometer-gyroscope module network (AGMN) **42**, bio-impedance module **44**, and a central hardware unit **46**.

The AGMN **42** comprises three accelerometer-gyroscope modules **42** located on the garment **36**. For the legging form factor of the smart compression garment **36**, these are placed on each upper thigh **14** and the lower back **50**. These modules **42** are a small electromechanical device that measures static and dynamic acceleration forces. These sensors **42** are highly sensitive and commonly used in missiles, cell phones, and other devices to determine the orientation of the device in three-dimensional space. The data collected from these modules may be utilized to classify the activity of the user **22** (e.g. walking, sitting, running, standing, sleeping, elevating the extremity, and others). In addition, this data is utilized to select times to collect impedance measurements from the user. Each of these sensors **42** may be encased in an enclosure, for example a small plastic enclosure made via injection molding. The water-resistant enclosure may protect the device from damage due to abrasion, impact, or water. These enclosures may be attached to the compression garment **36** via hook and loop fastener such as Velcro®, a clip, or some other fastener which may allow the enclosure to be removed and replaced. The accelerometer-gyroscope modules' enclosures could potentially be left out without compromising their function, and thus without compromising the function of the device **20**.

Each accelerometer-gyroscope module **42** may be connected to the central hardware **46**. This may be accomplished via traditional wiring, textile electronic traces or conductive connections. The central hardware may therefore collect all data from the AGMN **42** and may power the AGMN **42**. Instead of using accelerometer gyroscope units, other means of monitoring orientation of the device could be used, for example magnetometers or any combination of accelerometers, magnetometers, and gyroscopes. Instead of using only three accelerometer gyroscope units, more or fewer units could be utilized in the wearable sensor network.

As illustrated in FIG. **9**, the central hardware unit **46** comprises the central hardware **46**, central enclosure **38**, and textile-enclosure harness **58**. Connection, connector or adapter are envisioned as replacements for the harness. This central hardware unit **46** supplies power to all hardware, controls the AGMN **42** and the bio-impedance module **44**, temporarily stores data, and transmits all data collected in raw, analyzed, encrypted, or other form to the mobile application. The central hardware **46** has several subsystems including an impedance converter **60** and network analyzer (bio-impedance module) **44**, active analog filters **62**, power management integrated circuits **64**, multiplexed digital controls **66**, a wireless transmission module **68**, an analog to digital converter **70**, a microcontroller **72**, a peak detector **107**, an internal clock **108**, an SD card reader **109**, a serial-to-USB bridge **110**, a heart rate detector and a respiration monitor. The bio-impedance module **44** collects real and complex impedance data by delivering varying current magnitudes of up to 5 mA every 1 kHz across 5 kHz to 100 kHz s to the lower limb **74** and analyzing the delivered signal after it has passed through a section of tissue. A series of multiplexers **66** are utilized so that impedance analysis may be conducted on different segments of tissue by using different textile voltage-sensing electrodes **78** and current-injecting electrodes **80**. The current injection **80** and voltage sensing controls **78** result from active filters and multiplexers **76** that allow for different selection of stimulating current magnitude and sensing electrodes. All impedance measurements are taken via the tetrapolar electrode configuration **82** which minimizes the impact of variable skin-electrode contact impedances, polarization effects, and movement artifacts, since the voltage-sensing electrodes draw negligible current. These impedance measurements allow for a robust analysis of body composition of the lower limb, total body composition, swelling progression in the lower limbs, total body fluid retention, and patient compliance to compression therapy. Compliance is defined as when an individual is wearing the compression garment when instructed to by a medical professional. A battery **84** supplies the power required for all these functions and is rechargeable. Instead of a battery **84**, a capacitor or other component capable of storing energy and providing power could be used. Instead of providing information on charge of the device to the user, the device could provide that information to any other individual or entity or could omit providing such information. The wireless transmission module **68** relays data to the mobile application **88**. Instead of transmitting measured impedance values wirelessly, the device **20** could use a wired connection or other data relay mechanism to transmit measured values. The microcontroller controls all sensors and does minor data analysis.

Instead of utilizing the specific combination of hardware and software components listed here, other hardware and software components that allow for monitoring, transmission, recording, analyzing, or providing feedback on bio-impedance signals could be used. A temperature monitor or array of such monitors are also envisioned.

The central enclosure is a plastic (or other material) container holding the central hardware **46** created by injection molding (or another method). Its primary function is to protect the hardware from damage, for example that caused by abrasion, impact, or water exposure. It has ports to allow the enclosure to be snapped onto or otherwise fastened to the textile-enclosure harness and the hardware to be charged. Instead of a port to charge the device, wireless inductive charging could be utilized. Instead of using charging to power the device, the device could be powered continuously without charging, for example by using a wired plug.

This textile-enclosure harness **58** may both securely fasten the enclosure to the textile layers and allow the enclosure to be removed during garment laundering or for transfer to replacement garments. This harness may facilitate signal transfer between the central hardware/enclosure and the compression garment. This harness may be created by injection molding and may be laminated to the compression garment, stitched to the compression garment, or be held on to the compression garment via a pouch of fabric, among any other joining mechanisms.

The mobile application **88** will receive data from the smart compression garment **36** and will further transmit this data for analysis to an online server. Instead of transmitting data to an application or a server, data could be kept locally on the device **20**. Instead of performing data analysis remotely for example in an application or on a server, data analysis could be performed anywhere, for example locally on the device. This mobile application **88** will provide a certain amount of data analysis, display data to the user of the smart compression garment, provide the user with an understanding of the charge of the smart compression garment, and solicit information from the user **22**. Instead of providing data and/or feedback through an application, data and/or feedback could be provided directly on the device, for example though an LCD screen. Instead of providing data and/or feedback to the user, the application could provide data and/or feedback to an individual designated by the user **22**, a healthcare professional, an insurance company, or any other party with a legitimate interest in the user's healthcare or activity data.

The mobile application **88** is not required if the data-analyzing, data-recording, or feedback-providing functions of the device were incorporated into the device (central hardware unit **46** or similar).

Subjects may wear the WSN **28** while completing five simple and three complex tasks. These tasks may include walking, crawling, lying prone, running, climbing stairs, navigating a 2 ft. diameter cylinder, and turning to the left or right while walking. Additional complex tasks include: rappelling and hand-to-hand combat. The subjects may complete each task repetitively in a variety of environments, both indoors and outdoors, while carrying a variable amount of weight in a backpack. This may ensure data is collected for each task in a variety of terrains and conditions, allowing for robust classification. While the subject is completing these tasks, the WSN **28** may be collecting data from each SU **32** at 200 Hz. Each SU **32** may produce measurements of the x-, y-, and z-accelerations and the relative roll, pitch and yaw from the accelerometer and gyroscope, respectively. Therefore, the WSN **28** may collect 30 points of data per sample, 6 measurements from each of the 5 SUs **32**. There may be a minimum of 20,000 samples collected for each task. Each task dataset may be trimmed to an equal number of samples. After all data has been collected for each task, the task datasets may then be labeled and conglomerated via Keras Dataset package.

In preparation for training, the dataset may be shuffled and partitioned into two sections randomly. Two thirds of the data may be used to train the ANN **26** and one third may be used to validate the model. After the completion of this task, the overall model classification accuracy may be obtained along with each task classification accuracy. This methodology was successfully employed to classify simple tasks in the past with only one AGM **48** reading and may likely achieve greater accuracies with the addition of more sensors. In addition, the WSN **28** may investigate whether it is possible to remove data collected from some of the SUs **32** without significantly impacting classification accuracy. This may determine the minimal subset of biomechanical variables that allow the system to achieve the target performance for classifying tasks. This task may take 2 months to complete and may result in a LSTM-DRNN **90** capable of classifying all tasks, both simple and at least one complex, at a minimum of 80% accuracy.

This network **34** is a linear neural network **92** with an input layer (6 nodes) **93**, 4 hidden layers (75, 150, 450, and 150 nodes) **94**, and an output layer (4 nodes) **95**. The ANN **26** was initialized using PyTorch packages. A sigmoid function was utilized as the summing function and to introduce non-linearity into the model. The loss function utilized was mean-square loss. The optimizer was stochastic gradient descent. The dataset was partitioned to ensure the data utilized to train the model was not utilized to test and validate the model's accuracies. The ANN **26** was trained over 300 epochs with a batch size of 32 and a learning rate of 0.05 by first training a batch and then validating a batch to approach maximum accuracy. The overall network accuracy was 92.01%. The class accuracies were as follows: sitting: 85.61%, standing: 93.43%, sleeping: 94.42%, and elevating the leg: 95.13%. The validation and training loss may be seen in FIG. **5**. Each task accuracy and the overall network accuracy by epoch may be seen in FIG. **6**.

It is also possible to monitor the patient's compliance to compression therapy, since the ANN **26** and the BIS **96** system can each detect whether the patient is wearing the device. Furthermore, the ANN's **26** ability to distinguish between leg orientations and postures may allow the system to minimize the confounding effect of such changes on swelling measurement. This monitor may detect immobility and paralysis for the Wells Score (Table 1).

The proposed smart compression legging applies pressure identical to that of a waist-high compression stocking (40 mmHg at ankle, 15 mmHg at upper thigh) **14**. The legging may have two layers, each delivering half the required pressure (such pressures are additive). The interior layer may contain the textile electrodes **10**, which may be seamlessly knitted into the legging with a circular knitting machine. Such a machine can create a seamless garment from multiple types of fibers, in this case nylon fibers and the silver-coated nylon fibers that may act as the electrodes **10** and signal traces **106**. Alternatives to silver coated nylon fibers have been envisioned such as any other conductive fiber. Instead of conductive fiber, any means of reliably relaying a bioimpedance signal from electrodes **10** to central hardware **46**, for example wires or wireless electrodes, could be used.

The knitted fabric portions of the compression garment **36** exerts compression to the wearer's extremity. Fabric, cloth, or other wearable material may replace knitted fabric. Compression is provided through a manufacturing process where lycra or other elastic material is woven through the rest of the knitted material in such a way to allow the garment to exert pressure to the wearer when worn. Manufacturing processes other than circular knitting or injection-molding could be used. The relative density of lycra or other elastic material in a section of knitted material correlates to the pressure delivered. Typically, the compression garment is designed such that the pressure it exerts on the wearer gradually increases from a minimum at the most proximal aspect of the extremity covered by the garment to a maximum at the most distal aspect of the extremity covered by the garment. The most distal aspect of the extremity covered by the garment therefore represents the maximum pressure exerted, which is typically about 20 mmHg, about 30 mmHg, or about 40 mmHg. The most proximal aspect of the extremity covered by the garment typically has a corresponding minimum pressure of about 15 mmHg, about 20 mmHg, or about 30 mmHg, respectively. To achieve the optimal pressures, multi-layering of garments may be used. A zipper may be added to the end of the garment which provides the maximal pressure to enable the garment to be donned (put on) and doffed (taken off) easier. Alternatively, a section of non-elastic fabric may replace the most distal aspect of the garment. This non-elastic fabric may utilize a Velcro® flap to exert the desired amount of pressure and may be sewed onto the knitted fabric. The compression is not required to be medical-grade and a compression could be left out for non-medical uses.

The four electronic subcomponents of the compression garment **36** transmit signals between the wearable sensor network **28** and the lower limb **74** of the user **22**. These components are textile voltage-sensing electrodes **78**, textile current-injecting electrodes **80**, textile electronic vias **98**, and textile electronic traces **100**. In order to incorporate the four electronic subcomponents, the compression garment **36** may have two layers, each delivering half the required compressive pressure (such pressures are additive). Instead of stitched electronic vias **98**, seamless knitting, soldering, or any other joining mechanisms could be used to join the signal traces **106** to the electrodes **10**.

The interior layer may contain the textile electrodes **10**, which may be knitted into the garment **36** with a circular knitting machine or a flat knitting machine. Such machines can create a seamless garment from multiple types of fibers, in this case nylon fibers and the silver-coated nylon fibers that may act as the electrodes, electronic traces, and electronic vias. Circular current-injecting band electrodes **80** lie on the most proximal aspect of the extremity covered by the garment and the most distal aspect of the extremity covered by the garment. These textile current-injecting electrodes **80** are defined as the patches of silver-coated nylon fabric (silver fabric) which transmit current to the extremity for bioimpedance spectroscopy. These electrodes may be fashioned in a circumferential band of silver fabric material **102** on the interior layer of the garment, in a rectangular patch of silver fabric material on the interior layer, or in other configurations. These electrodes must be in contact with the skin to properly function. At least two voltage-sensing electrodes **78** lie on each extremity **104** between each pair of current-injecting band electrodes **78**. These textile current-injecting electrodes **78** are defined as the patches of silver-coated nylon fabric which transmit voltages of the extremity for bioimpedance spectroscopy. These electrodes **10** may be fashioned in the same forms as, or in other forms than, the textile current-injecting electrodes **78**.

The exterior layer of the garment may contain the silver signal traces **106** connecting the textile electrodes **10** of the interior layer to the central hardware **46** on the lower back **50**. Such traces **106** eliminate the need for bulky wires in the legging. These traces **106** are defined as the lines of silver-coated nylon fabric which overlay the textile electrodes **10** in the internal layer of the compression garment **36** and which run to the central hardware **46** of the wearable sensor network **28**. These textile traces **106** of the compression garment **36** are connected to traditional circuit elements of the wearable sensor network **28** by soldering conductive fibers from each trace to the hardware, utilizing metal snaps, utilizing ribbon cable connectors, utilizing raised wire connectors, or utilizing other methods.

Manufacture of Compression Legging System:

Step 1: Assembling the Garment Layers **36**

The two layers (interior and exterior) may be stitched together for stability, as may the locations where the signal traces **106** and the electrodes **10** touch. These strategies were successfully employed to create FDA-approved ECG electrodes **10** capable of capturing and transferring high-quality signals. Instead of two layers, more or fewer layers of a garment could be utilized to achieve the same results.

Step 2: Assembling the Garment Layers

The interior and exterior layers may be stitched together for mechanical stability, electrical insulation between the skin and electrical textile traces **100**, and signal transmission between textile electronic traces **100** and textile electrodes **10**. The locations where the signal traces **106** and the electrodes **10** touch may be stitched together to ensure signals may transmit properly between the external and internal layers of the compression garment. These stitches are considered to be the textile electronic vertical interconnect accesses (vias) **98**, which are defined as electrical pathways which allow signals to be conducted between layers of the garment.

Step 3: Installing Information Transfer Application

The proposed smart compression legging **36** may be Bluetooth-interfaced or otherwise wirelessly interfaced or interfaced with a wired connection with a mobile application to provide readings to the patient. The back-end of the application may utilize Amazon Web Service's (AWS) security, database and analytics features. AWS is fully equipped to handle patient data, is scalable, and is commonly used in healthcare. Patients with PTS may use the application **88** to detect recurrent DVT and to provide information for the Wells Score (Table 1) including which of their legs is affected by PTS, the presence of collateral superficial veins, scores for pain or tenderness in their leg, the date of a recent surgery, their history of cancer, their history of cast immobilization, and the presence of pitting edema. The patient's primary care physician may aid the patient in this task. Additionally, a questionnaire developed with emergency medicine providers may be utilized to determine if an alternative diagnosis is as likely as DVT (Table 1).

Elevating the leg causes fluid to leave the leg due to gravity. This phenomenon was used to validate that the system's current tetrapolar BIS prototype ("alpha prototype") **96** can detect swelling in the leg. Instead of using the tetrapolar electrode configuration **82**, any other electrode configuration could be used. FIG. **2** details preliminary studies conducted using the system to demonstrate the performance of its impedance-measuring applications. Subjects (N=5) followed a testing protocol to study the effect of leg position on extracellular fluid changes labeled as 1) "Leg Down" (leg hovering with gravitational vector) and 2) "Leg Up" (leg raised against gravitational vector). The "Leg Down" test was conducted first. During each test, subjects **23** were indicated to remain in the specified position for 2 minutes prior to initiating the multi-frequency bioimpedance analysis. The multi-frequency (5 kHz-100 kHz) bioimpedance analysis was conducted for a total of 2 minutes, where samples were recorded every 30 seconds. Each test was repeated in triplicates with a 1-minute resting period between each reading. In total, there were 4 readings per test, totaling to 12 readings per position study. Data was analyzed to calculate impedance per frequency with a corresponding 95% confidence interval to demonstrate statistical significance per frequency and subject.

More frequencies are envisioned including below 5 kHz and above 100 kHz. Instead of sampling every 1 k Hz, data could be sampled frequently (e.g. every 2 kHz or every 500 Hz or at irregular intervals).

The system was used to conduct a preliminary feasibility study of the ability of an accelerometer-trained artificial neural network (ANN) **26** to differentiate between different leg orientations. A healthy human subject wore the alpha prototype and sat, stood, slept, or elevated the leg while a total of 43,865 acceleration measurements were taken. An ANN **26** was trained with all data samples over 150 epochs. The training and validation loss validated that the network was trained appropriately (i.e. not over or under trained). The ANN **26** successfully distinguished between sitting, standing, sleeping, and elevating the leg over 95% of the time (all class accuracies are >95%), allowing for robust patient activity monitoring.

The system uses fabricated textile voltage-sensing (**78** in FIG. **3**) **78** and current-injecting electrodes (**80** in FIG. **3**) **80** for impedance measurement. Voltage-sensing electrodes **78** were constructed from 0.75"×0.75" patches of silver conductive fabric (LessEMF, #A321), while current-injecting electrodes **80** were formed from 0.75" wide, 10"-20" long circular bands of the same fabric. Electrodes **10** were adhered to the interior of a compression garment with fabric glue and interfaced to the rest of the alpha prototype with metal snaps. Snaps were insulated from the skin with electrical tape during testing.

The performance of these electrodes in making BIS **96** measurements with TEC **82** was compared to that of standard FDA-approved adhesive Red Dot™ electrodes (3M, #2560) using the alpha prototype. Four impedance measurements were taken from a healthy human subject at each kHz frequency from 5 kHz to 100 kHz. Six (6) replicates were performed for voltage-sensing electrodes **78** and four (4) replicates for current-injecting electrodes **80**. A two sample, two-tailed T-test was conducted at each frequency. Results indicated that the system's textile electrodes gave impedances no statistically significant difference from those obtained with Red Dot™ electrodes at 72% of all frequencies evaluated (alpha=0.05).

Alternative uses of the system have been envisioned including determining ideal fit for a bespoke garment, full body strain measurements, pressure mapping anywhere on the body such as under foot, pulse monitor (pressure sensors), respiration monitor (transthoracic impedance), monitoring orthopedic health in the leg (detecting synovium swelling changes), cartilage health monitor, muscle activity monitor via the voltage sensing electrodes, EKG monitor in a compression shirt with voltage sensing electrodes, monitoring venous return in anti-gravity straining maneuvers, and monitoring fluid redistributions in mechanical counter-pressure suits.

A wearable sensor network (WSN) **28** may be constructed to gather biomechanical data. As illustrated in FIG. **7**. WSN **28** may include five sensor units (SUs) **32**, each containing a single six-axis accelerometer-gyroscope module (AGM) **42**. A six-axis AGM **42** is a small electromechanical device that measures static and dynamic acceleration forces. These sensors **42** are highly sensitive and commonly used in missiles, cell phones, and other devices to determine the orientation of the device in three-dimensional space. A microcontroller unit (MCU) **72** may operate each SU **32** and may harvest and save parameters obtained at a 200 Hz sampling rate. Several strategies are envisioned to determine the optimal method to attach the WSN **28** to a subject such as hook and loop fasteners such as Velcro®, embedded sensors, straps, and safety pins.

Optimizations for the WSN **28** may include: the addition of more AGMs **42**, the removal of AGMs **42**, the addition of other physiological sensors (e.g. electromyograms) and replacing flat wires with Bluetooth communicators. Optimizations for the ANN **28** may include: pre-processing of data to extract features, analyzing acceleration and gyroscope data points separately, and altering the existing architecture.

The WSN **28** may be constructed using commercial off-the-shelf components including existing AGMs **42** and printed circuit boards to ensure the circuit performs as expected. Custom enclosures **38** may be designed and 3D-printed for each SU **32**, the MCUs **72** and batteries **84** to reduce impacts, abrasion and dirt from damaging the circuitry. In addition, enclosures **38** may ensure the wiring connecting the SUs **32** on the lower limbs and torso to the MCU **72** on the torso may remain in place during movement.

The anatomical position of the WSN **28** may be seen in FIG. **7**. Three SUs **32** containing AGMs **42** may be placed on each proximal posterior thigh of the soldier and the posterior lower back. An MCU **72** may be located on the posterior lower back and may connect to those three SUs **32** via flat wiring. Instead of placing the MCU **72** on the lower back, it could be placed anywhere on the garment such as on the thighs. Instead of a central hardware enclosure on the garment, hardware could be located off the garment and could receive all necessary signals wirelessly. Instead of a single central hardware, the device could be split into several enclosure units to reduce size and minimize ergonomic issues.

Two additional SUs **32** may be located on each wrist. Two MCUs **72** may control each of these SUs **32**. The relative position and acceleration of a soldier's center of gravity, upper thighs, and wrists are unique during the execution of a given task, and this configuration has been successfully utilized to classify complex and simple tasks. This task may result in a WSN **28** capable of collecting biomechanical data from a soldier.

The classification model may be utilized to detect blood clot formation in patients suffering from post-thrombotic syndrome (PTS).

While this disclosure has been described as having an exemplary design, the present disclosure may be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the disclosure using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this disclosure pertains.

What is claimed:

1. A system for detection of a human disease, wherein the system comprises:

a compression garment, the compression garment comprising a wearable sensor network and an application;

the wearable sensor network comprising a plurality of electrodes,

wherein four electrodes of the plurality of electrodes are configured to be alternately and ipsilaterally activated in each leg of a user,

wherein the four electrodes are configured to be activated in a configuration consisting of two current-injecting electrodes and two voltage-sensing electrodes;

and the wearable sensor network comprising a multiplexor configured to sequentially alternate which two electrodes of the four electrodes are activated as the voltage-sensing electrodes, enabling a data collection and a data analysis from a plurality of different locations of each leg of the user,

the collected data comprising ipsilateral bio-impedance measurements of each location of the plurality of different locations of each leg of the user, and each location of the plurality of different locations of each leg of the user positioned between the two voltage-sensing electrodes;

wherein the wearable sensor network further comprises a central hardware unit,

wherein at least one accelerometer-gyroscope module and at least one bio-impedance module are connected to the central hardware unit by wiring, textile electronic traces, or conductive connections;

the at least one bio-impedance module configured to collect the ipsilateral bio-impedance measurements from each location of the plurality of different locations of each leg of the user positioned between the two voltage-sensing electrodes,

and the at least one accelerometer-gyroscope module configured to collect an additional data set from the user,

the additional data set comprising acceleration and gyroscopic data from each leg of the user;

wherein the central hardware unit is configured to

supply power to the at least one accelerometer-gyroscope module and to the at least one bio-impedance module;

to temporarily store the ipsilateral bio-impedance measurements from the bio-impedance module and the additional data set from the at least one accelerometer-gyroscope module;

and to transmit the ipsilateral bio-impedance measurements and the additional data set to a mobile application,

wherein the mobile application is configured to receive a third data set from additional modules and to further transmit the ipsilateral bio-impedance measurements, the additional data set, and the third data set to an online server;

wherein the bio-impedance module is configured to collect the ipsilateral bio-impedance measurements by delivering a plurality of current signals to each location positioned between the two voltage-sensing electrodes of each leg of the user,

the plurality of current signals having varying current magnitudes of up to 5 mA every 1 kHz across 5 kHz to 100 kHz;

and is further configured to analyze the plurality of delivered current signals after the plurality of delivered current signals have passed through a section of tissue at each location positioned between the two voltage-sensing electrodes of each leg of the user.

2. The system of claim **1**, wherein the system is configured to take the ipsilateral bio-impedance measurements from each location positioned between the two voltage-sensing electrodes in real-time, while the user performs activities.

3. The system of claim **1**, wherein each electrode of the plurality of electrodes of the wearable sensor network is encased in an enclosure including plastic,

wherein the enclosure is manufactured by injection-molding,

wherein the enclosure is configured to protect the network from damage arising from abrasion, impact, and water.

4. The system of claim **1**, wherein the system is further configured to detect and classify movements of each leg of the user.

5. The system of claim **1**, wherein the central hardware unit further comprises a central enclosure and a textile-enclosure harness.

6. The system of claim **5**, wherein the textile-enclosure harness is configured to be removably coupled to the central enclosure.

7. The system of claim **1**, wherein the central hardware unit comprises an impedance converter, a neural network analyzer, a plurality of active analog filters, a plurality of power management integrated circuits, a plurality of multiplexed digital controls, a wireless transmission module, an analog to digital converter, and a microcontroller

the microcontroller configured to control the plurality of electrodes and to perform the data analysis

and wherein the mobile application is further configured to provide the data analysis, display the collected data to the user, transmit a battery charge of the garment, and solicit an input from the user.

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